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DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1423

RIN 0560–AI18

Clarification of Bales Made Available for Shipment by CCC-Approved Warehouses

AGENCY: Commodity Credit Corporation and Farm Service Agency, USDA.

ACTION: Final rule.

SUMMARY: This rule amends the regulations that specify the requirements for the Commodity Credit Corporation (CCC)-approved warehouses storing cotton, which are administered by the Farm Service Agency (FSA). FSA is changing the definition of Bales Made Available for Shipment (BMAS). CCC-approved cotton warehouses are currently required to report BMAS, among other data, to FSA every week. FSA is clarifying that bales made available, but not picked up by the shipper, can only be reported by the warehouse operator as BMAS for no longer than the first 2 weeks that such bales have been made available for delivery but have not yet been picked up. This rule change includes whether bales not picked up are reported by the warehouse operator to FSA in the weekly report; it does not change any warehouse tariffs, late fees, or restocking fees. The quality of reported information about bales made available for shipment will improve, which will benefit both FSA and the cotton industry.

DATES: *Effective Date:* December 31, 2014.

FOR FURTHER INFORMATION CONTACT: Dan Schofer, telephone: (202) 720–2121. Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact the USDA Target Center at (202) 720–2600 (voice and TDD).

SUPPLEMENTARY INFORMATION: The Commodity Operations Division of FSA administers the CCC-approved warehouse program for CCC. This responsibility includes approving and licensing warehouses where commodities that are under various types of CCC loans may be stored. Those approved warehouses are required to comply with CCC regulations, which include reporting information about the stored commodities to FSA. The specific requirements that approved warehouses must meet are specified in the regulations in 7 CFR part 1423, ''Commodity Credit Corporation Approved Warehouses,'' and in the written storage agreements between CCC and the warehouse for each type of commodity.

CCC-approved cotton warehouses are currently required to report BMAS, among other data, to FSA every week. This rule will clarify that bales made available, but not picked up may only be reported as BMAS for no longer than the first 2 weeks that such bales were made available for shipment. The rule only changes how bales not picked up are counted in the weekly report to CCC; it does not change any warehouse tariffs, late fees, or restocking fees.

As specified in this rule, bales made available for shipment, but not picked up may not be reported as BMAS for longer than the first 2 weeks that such bales were made available for shipment. There was no such time limit in the previous regulations or in the previous Cotton Storage Agreement (CSA) between FSA and approved warehouses. FSA is clarifying how BMAS is defined in the regulations in 7 CFR 1423.11 that apply to CCC-approved cotton warehouses; a conforming change will be made to Amendment 2 of CCC's CSA. CSA is the agreement between CCC and the warehouse on the requirements that the warehouse must meet for storing cotton that is under loan to CCC. The standard CSA form and the subsequent amendments are available on FSA's Web site at *http://www.fsa.usda.gov/FSA/webapp?area=home&subject=coop&topic=was-ca.*

There is no expected cost to warehouses or CCC of reporting BMAS as specified in this rule. Since very few cotton warehouses currently list BMAS for longer than 2 weeks, this rule will not affect the majority of warehouse operators. The rule will only change how bales made available for shipment, but not picked up by the shipper are reported by the warehouse operator to CCC in the weekly report, it does not change warehouse tariffs or restocking fees.

This change is intended to make the flow of cotton from U.S. producers and cotton warehouses to shippers, and ultimately to cotton merchants, more efficient based upon more accurately knowing and reporting what cotton is available for shipment. Availability and consistent supply of cotton are crucial for the U.S. cotton, and having accurate information about bales available for shipment contributes to an efficient supply of U.S. cotton.

Discussion of Comments

In response to the proposed rule, eight comments were submitted by commenters during the 60-day comment period. Comments were submitted by cotton industry associations, association members, and an individual cotton warehouse. Seven of the eight comments support the proposed rule change. Most of the supportive comments expressed the feeling that the proposed rule change will strengthen USDA enforcement of the current shipping standard requirement of 4.5 percent of a warehouse's applicable storage capacity per week.

One of the supportive comments offers a suggestion for an additional change. One commenter disagrees with the proposed rule change. The following provides a summary of public comments received on the proposed rule and FSA's responses.

Comment: Only count a bale once in flow calculation—when the load is first assembled (broken out), rather than counting it again if unloaded and reloaded at a transit warehouse.

Response: Warehouse operators report the number of bales shipped, made available for shipment, or not picked up in the weekly BMAS report. Warehouse operators are not required to list bales individually in the BMAS report, nor is the reporting format set up to handle that amount and type of data. There will be no change in response to the comment.

Comment: Bales made available for delivery, but not picked up should stay a part of the BMAS total until shipment;

they should not be removed from the report after only 2 weeks.

Response: The flow of cotton from warehouses will continue regardless of the amount of bales not picked up; the change in the definition and the resulting change in the reporting will not change that. Warehouses are still required to deliver, schedule, and have cotton bales ready for delivery without unnecessary delay. In order to be considered to have delivered cotton without unnecessary delay, the warehouse operator must make available for shipment at least 4.5 percent of the applicable storage capacity in effect during the relevant week of shipment. Accurate BMAS data and cotton flow information contributes to the efficient supply of U.S. cotton. It could be detrimental to the cotton industry as whole if BMAS data gave the appearance that cotton is flowing at a steady, consistent rate, but in reality months of cotton bales not picked up remain in warehouses across the country. In order to improve the quality of reported information about bales made available for shipment, there will be no change in response to the comment.

Executive Order 12866 and 13563

Executive Order 12866, ''Regulatory Planning and Review,'' and Executive Order 13563, ''Improving Regulation and Regulatory Review,'' 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The Office of Management and Budget (OMB) designated this rule as not significant under Executive Order 12866 and, therefore, OMB has not reviewed this rule.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), generally requires an agency to prepare a regulatory flexibility analysis of any rule whenever an agency is required by APA or any other law to publish a proposed rule, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. FSA is certifying that this rule would not have a significant economic effect on a substantial number of small entities. New provisions in this rule would not impact a substantial number of small entities to a greater extent than large entities. Therefore, FSA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Environmental Review

The environmental impacts of this rule have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321–4347), the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and FSA regulations for compliance with NEPA (7 CFR part 799). This rule would only change how bales not picked up are counted in the weekly report to CCC and does not change the structure or goals of the program and can be considered simply administrative in nature. Therefore, FSA has determined that NEPA does not apply to this proposed rule and no environmental assessment or environmental impact statement will be prepared.

Executive Order 12372

Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' requires consultation with State and local officials that would be directly affected by proposed federal financial assistance. The objectives of the Executive Order are to foster an intergovernmental partnership and a strengthened Federalism, by relying on State and local processes for State and local government coordination and review of proposed Federal Financial assistance and direct Federal development. For reasons set forth in the final rule related document regarding 7 CFR part 3015, subpart V (48 FR 29115, June 24, 1983), the programs and activities within this rule are excluded from the scope of Executive Order 12372.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, ''Civil Justice Reform.'' This rule will not preempt State or local laws, regulations, or policies unless they represent an irreconcilable conflict with this rule. This rule will not have retroactive effect. Before any judicial action may be brought regarding provisions of this proposed rule, the administrative appeal provisions of 7 CFR parts 11 and 780 must be exhausted.

Executive Order 13132

This rule has been reviewed under Executive Order 13132, ''Federalism.'' The policies contained in this rule would not have any substantial direct effect on States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, except as required by law. Nor does this rule impose substantial direct compliance costs on State and local governments. Therefore, consultation with the States is not required.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects 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.

FSA has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under Executive Order 13175. If a Tribe requests consultation, FSA will work with the USDA Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified in this rule are not expressly mandated by the 2014 Farm Bill.

Unfunded Mandates

Title II of the Unfunded Mandate Reform Act of 1995 (UMRA, Pub. L. 104–4) requires Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments, or the private sector. Agencies generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with Federal mandates that may result in expenditures of $100 million or more in any 1 year for State, local, or Tribal governments, in the aggregate, or to the private sector. UMRA generally requires agencies to consider alternatives and adopt the more cost effective or least burdensome alternative that achieves the objectives of the rule.

This rule contains no Federal mandates as defined by Title II of UMRA for State, local, or Tribal governments, or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

SBREFA

This rule is not a major rule under the SBREFA (Public Law 104–121). Therefore, FSA is not required to delay the effective date for 60 days from the date of publication to allow for Congressional review. Accordingly, this rule is effective 30 days after publication in the **Federal Register**.

Paperwork Reduction Act

The cotton information covered in this rule is the weekly reporting of BMAS by cotton warehouses. BMAS is reported through the Electronic Warehouse Receipt (EWR) system, to which FSA has access. EWR is operated by a private company and generally contains information that is exempt from the Paperwork Reduction Act (44 U.S.C. Chapter 35) because it is usual and customary business information. The change in the regulation would not change the burden associated with reporting BMAS, which is required to be reported weekly. The only thing that would change is which bales are required to be included in the calculation of the total BMAS for that week. EWR is approved under OMB control number 0560–0120.

E-Government Act Compliance

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

List of Subjects in 7 CFR Part 1423

Agricultural commodities, Honey, Oilseeds, Reporting and recordkeeping requirements, Surety bonds, Warehouses.

For the reasons discussed above, 7 CFR part 1423 is amended as follows:

PART 1423—COMMODITY CREDIT CORPORATION APPROVED WAREHOUSES

■ 1. The authority citation for part 1423 continues to read as follows:

Authority: 15 U.S.C. 714b and 714c.

■ 2. Revise § 1423.11(b)(1)(ii) to read as follows:

§ 1423.11 Delivery and shipping standards for cotton warehouses.

* * * * *

(b) * * *

(1) * * *

(ii) Were scheduled and ready for delivery in a previous week, but were not picked up by the shipper and remain available for immediate loading and another shipping date has not been established, or such bales are not subject to a restocking fee as provided in the warehouse operator's public tariff. Bales that have been available for delivery but not picked up may be counted as BMAS for no longer than the first two weeks that such bales have been made available for delivery but not yet picked up by the shipper.

* * * * *

Dated: November 23, 2014.

Val Dolcini,

Administrator, Farm Service Agency, and Executive Vice President, Commodity Credit Corporation.

[FR Doc. 2014–28180 Filed 11–28–14; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, and 95

[Docket No. APHIS–2006–0074]

RIN 0579–AC36

Highly Pathogenic Avian Influenza

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are adopting as a final rule, with changes, an interim rule that amended the regulations concerning the importation of animals and animal products to prohibit or restrict the importation of live birds and poultry (including hatching eggs) and bird and poultry products from regions where any subtype of highly pathogenic avian influenza (HPAI) is considered to exist. The interim rule also added restrictions concerning importation of live birds and poultry that have been moved through regions where HPAI is considered to exist, or that have been vaccinated for certain types of avian influenza. This final rule amends the interim rule to allow the importation of live zoological birds and poultry that have been vaccinated for avian influenza as part of an official program and under specific conditions as determined by the Administrator and to allow the importation of HPAI-resistant pigeons, doves, and other Columbiform species under certain conditions from regions where HPAI is considered to exist. This action will provide for the importation of certain zoological birds and poultry under specified conditions designed to minimize the risk of introducing HPAI into the United States.

DATES: Effective December 1, 2014.

FOR FURTHER INFORMATION CONTACT: Mr. Javier Vargas, Case Manager, National Import Export Services, Animal Health Policy and Programs, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737; (301) 851–3300.

SUPPLEMENTARY INFORMATION:

Background

In an interim rule [1] effective and published in the **Federal Register** on January 24, 2011 (76 FR 4046–4056, Docket No. APHIS–2006–0074), we amended the regulations in 9 CFR parts 93, 94, and 95 [2] concerning the importation of animals and animal products to prohibit or restrict the importation of bird and poultry products from regions where highly pathogenic avian influenza (HPAI) is considered to exist by applying mitigations similar to those we use for Newcastle disease.[3] The interim rule included restrictions concerning importation of live birds and poultry (including hatching eggs) that have been vaccinated for certain types of avian influenza or that have been moved through regions where HPAI is considered to exist. In addition, the interim rule updated cooking requirements to specifically include carcasses, parts, or products of poultry or other birds from regions where HPAI is considered to exist. These actions were necessary to prevent the introduction of HPAI into the United States.

We solicited comments concerning the interim rule for 60 days ending March 25, 2011. We reopened the comment period [4] for 15 days ending May 18, 2011, to give commenters more time to respond. We reopened the

[1] To view the interim rule, supporting documents, the May 2011 and June 2012 documents reopening the comment period, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2006-0074.*

[2] On December 4, 2013, we published another rulemaking, ''Bovine Spongiform Encephalopathy; Importation of Bovines and Bovine Products'' (78 FR 72980–73008) that redesignated the sections we amended in part 95 in the interim rule. These redesignations are reflected in this final rule.

[3] The interim rule used the term ''exotic Newcastle disease'' or ''END.'' In this document, we have removed the word ''exotic'' from the term to reflect changes made to the regulations in a final rule published March 29, 2013 (78 FR 19080–19085).

[4] **Federal Register**, May 3, 2011 (76 FR 24793, Docket No. APHIS–2006–0074).

comment period a second time [5] for 30 days ending July 12, 2012, to solicit comments on allowing the importation of pigeons, doves, and other Columbiform species from regions considered to have HPAI after establishing that importation of these species poses a low risk of introducing HPAI into the United States.

We received a total of 19 comments during those three comment periods. Commenters included a State veterinary official, a foreign government official, veterinarians, associations representing U.S. zoos and zoo veterinarians, an ornithological research organization, egg industry representatives, a restaurant chain, and the general public. A consumer food safety organization commented by submitting a letter with 17,540 copies signed by members of the public.

We have carefully considered the comments we received. Three commenters expressed concerns about the risk of HPAI but did not substantively address any specifics of the interim rule. The remaining comments are discussed below by topic.

General Comments

One commenter objected to our issuing an interim rule instead of a proposed rule, noting that we made effective the action to prohibit or restrict the importation of live birds and poultry, and bird and poultry products, from regions where HPAI is considered to exist without first soliciting public comments.

Immediate action was necessary to prevent the introduction of HPAI into the United States. Under those circumstances, we determined that prior notice and opportunity for public comment were contrary to the public interest and that there was good cause under 5 U.S.C. 553(b)(B) for making the interim rule effective upon publication in the **Federal Register**.

In the interim rule, we requested comment on whether the list of regions considered to be free of Newcastle disease in 9 CFR 94.6(a)(1) should be removed from the regulations and posted on the Animal and Plant Health Inspection Service (APHIS) Web site, as we have done with similar lists of regions.

Two commenters agreed with the idea and no commenters objected.

Accordingly, this final rule amends the regulations to remove the list of regions considered to be free of Newcastle disease from 9 CFR 94.6(a)(1)(i) and adds text referring readers to the list on the APHIS Web site.[6]

A region will be removed from the list of regions considered to be free of Newcastle disease whenever we receive reliable reports of disease outbreaks in commercial birds and poultry from veterinary officials of the national government of the region and/or the World Organization for Animal Health (OIE). The Administrator of APHIS may also remove a region from the list based on outbreak reports of Newcastle disease that he or she receives from other reliable sources, such as APHIS inspectors based in foreign countries. This approach will allow us to quickly update the list on the Web site whenever necessary without needing to amend the CFR, which can take much more time to do.

A region removed from the list of regions considered to be free of Newcastle disease on the APHIS Web site may be reinstated to the list in accordance with the procedures for reestablishing a region's disease-free status set forth in 9 CFR 92.4 of the regulations.

Importation of Live Birds and Poultry

The importation into the United States of live birds and poultry, including eggs for hatching, is subject to the regulations in part 93, Subpart A—Birds (§§ 93.100–93.107) and Subpart B—Poultry (§§ 93.200–93.220).

A commenter requested that APHIS provide an exception to its prohibition on live birds and poultry from regions where HPAI is considered to exist by permitting the entry of birds and poultry that have been quarantined and tested prior to export to the United States in a manner consistent with our own post-import quarantine and testing procedures.

We are taking no action in response to this request. Our established import quarantine procedures have been proven to be effective and offer a predictable measure of assurance supported by testing in approved laboratories using appropriate diagnostic methods. Quarantine and testing procedures conducted overseas may not always adequately address APHIS requirements and would be impractical and resource-intensive.

However, we have determined that it is necessary to amend the live bird and poultry regulations in the interim rule to reflect changes we made in another rulemaking. In a March 2013 final rule that recognized 25 Member States of the European Union (EU) as the APHIS-defined EU poultry trade region,[7] we amended the regulations to allow the importation of hatching eggs that have transited a zone restricted for HPAI within that region. To make the regulations consistent with this change, we are amending the general prohibitions in 9 CFR 93.101(a) for birds and hatching eggs of birds, and 9 CFR 93.201(a) for poultry and hatching eggs of poultry, to indicate that unless specifically indicated otherwise in the regulations,[8] no live birds or poultry, and no hatching eggs from birds or poultry, shall be imported into the United States if the birds or poultry (or the flocks of origin in the case of hatching eggs) originated from or transited a region identified in accordance with 9 CFR 94.6(a) as a region where any form of HPAI or Newcastle disease is considered to exist. As 9 CFR 93.201(a) prohibits importation of hatching eggs of poultry that have originated in or transited regions where these diseases exist other than the APHIS-defined EU poultry trade region, we are also amending 9 CFR 93.205(b) to require that the import certificate state that the hatching eggs have not been moved through a region identified in accordance with § 94.6(a) as a region where any form of HPAI exists. This statement is already required on certificates for live poultry in 9 CFR 93.205(a).

We are also amending paragraphs (b)(7), (c)(11), and (d)(7) of the certification requirements for importing live birds in 9 CFR 93.104 to replace ''previously unused containers'' with ''new or appropriately sanitized packaging materials.'' Similarly, we are amending paragraphs (a) and (b) of 9 CFR 93.205 to make this same change in the certification requirements for importing live poultry and hatching eggs of poultry. This change allows for more flexible packaging options and provides additional risk mitigation for imported poultry and hatching eggs.

Finally, to emphasize that testing for avian influenza is currently a part of our routine health certification and quarantine requirements for imported birds, we are amending these requirements in 9 CFR 93.101, 93.104, and 93.106 to include references to avian influenza.

[5] **Federal Register**, June 12, 2012 (77 FR 34783–34784, Docket No. APHIS–2006–0074).

[6] *http://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml.*

[7] **Federal Register**, March 29, 2013 (78 FR 19080–19085, Docket No. APHIS–2009–0094): *http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0094.*

[8] The Administrator, under 9 CFR 93.101(a), may also allow pet or other birds to transit regions where any form of HPAI is considered to exist, under stipulated conditions provided in a permit, when a determination is made that such importations will not endanger livestock or poultry health in the United States.

Importation of Columbiform Species From Regions Where HPAI Is Considered To Exist

As noted above, we reopened the comment period on the interim rule for 30 days [9] to solicit comments on a change that would allow live pigeons, doves, and other Columbiform species to be imported under certain conditions to approved establishments from regions where HPAI is considered to exist. We considered this change because peer-reviewed scientific studies [10] have come to our attention since the publication of the interim rule establishing that Columbiform species have a very low risk of being infected by HPAI viruses. We have carefully reviewed these studies and concluded that importation of such species to approved establishments would constitute a low risk of introducing and spreading HPAI viruses in birds and poultry.

One commenter, a State veterinary official, stated that there appear to be no restrictions in the rule on how Columbiform species are to be housed and transported within a zone where HPAI is considered to exist. The commenter stated that non-Columbiform species of birds and poultry could be crated next to Columbiform species during transport and be on- and off-loaded from or within the zones of infection. The commenter added that even though Columbiform species from HPAI-affected regions have a low risk of becoming infected, those species and their crates could serve as fomites and transmit the virus to more susceptible species of avians if commingled with them at any point during importation or quarantine. For this reason, the commenter requested that we not allow importation of any Columbiform species that have been moved through regions where HPAI is considered to exist.

While it is possible that Columbiform species could transmit the HPAI virus to non-Columbiform species via fomites, we consider our existing risk mitigations regarding fomites and commingling sufficient to allow importation of Columbiform species that have been moved through regions with HPAI. Title 9 CFR 93.204 establishes that for the importer to obtain a permit, he or she must provide information that includes the species, breed, and number of poultry to be imported and the region of origin, as well as the mode of transportation and the route of travel. APHIS would not issue an import permit if the conditions of importation were such that Columbiform species (and their fomites) from regions considered to have HPAI were commingled, quarantined, or otherwise directly or indirectly exposed at any point with non-Columbiform species.

However, we acknowledge the commenter's concern about commingling and are adding a provision to the certificate requirement to 9 CFR 93.205(a) for Columbiform species that have been moved through regions considered to have HPAI. Except for the requirement prohibiting movement through such regions, Columbiform species intended for importation into the United States are subject to all other certificate requirements listed in 9 CFR 93.205(a) as amended by this document. The certificate requirement we are adding to 9 CFR 93.205(a) states that pigeons, doves, and other Columbiform species that have originated from or been moved through regions where HPAI is considered to exist were moved and handled under conditions specified on an import permit ensuring that their movement and handling involved no direct or indirect exposure to other animals, birds, and poultry.

Prohibition on Day-Old Chicks and Hatching Eggs Transiting Regions Where HPAI Is Considered To Exist

Three commenters opposed the prohibition in the interim rule on the importation into the United States of day-old chicks and hatching eggs that have transited regions where HPAI of any subtype is considered to exist.

One commenter stated that day-old chicks are commonly flown in sealed containers between continents and expressed concern about whether such chicks would still be eligible for importation into the United States if the flight touched down briefly at an airport in a region considered to have HPAI. Another commenter noted that EU regulations allow transit of live poultry, including day-old chicks and hatching eggs, through zones under restrictions for HPAI on the condition that transport takes place on roads or rail without unloading or stopping. The commenter stated that if the day-old chicks are moved under strictly controlled, biosecured, and air-conditioned circumstances, with no need to provide feed and water during transport, the risk of their exposure to HPAI is minimal.

We disagree with the commenters with regard to importing day-old chicks that have transited regions where HPAI is considered to exist. Unlike Columbiform species, day-old chicks of other poultry species are highly susceptible to contracting HPAI and therefore more likely to harbor and transmit the virus to other birds or poultry. Water or feed present during transit may also become contaminated. Scientific evidence indicates that secondary spread of avian influenza viruses mainly occurs through mechanical transfer of feces from infected birds, in which the virus may be present at high concentrations and may survive for considerable periods, and that the virus may be spread by birds, poultry, or other animals not themselves susceptible to infection becoming contaminated in transit through contact with infected birds and poultry [11] (which is why, as a condition of entry, Columbiform species will not be allowed to be commingled with birds of any other species during transport). Consequently, there is a significant risk of day-old chicks contracting HPAI if they are moved through regions where HPAI is considered to exist en route to the United States.

While we consider movement of day-old chicks through regions affected by HPAI to pose an unacceptable import risk, we acknowledge that hatching eggs can be moved through regions affected by HPAI at a sufficiently low level of risk if we determine that the controlling authority of that region has instituted sufficient risk mitigation measures. Accordingly, in a March 2013 final rule [12] that recognized 25 Member States of the EU as the APHIS-defined EU poultry trade region, we amended the regulations to allow the importation of hatching eggs that have transited a zone restricted for HPAI within that region. Given the control measures that are uniformly and effectively enforced by the EU, the risk of exposure of hatching eggs to HPAI while transiting zones within the APHIS-defined EU poultry trade region is very low as long as all measures in the import permit issued by APHIS are followed and the shipment is sealed by the veterinary competent authority. All hatching eggs must be quarantined from time of arrival at the port of entry until hatched as required in 9 CFR 93.209, and the poultry from such eggs will remain quarantined for not less than 30 days following hatching. During their quarantine, eggs for hatching and poultry from such eggs will be subject to any inspections,

[9] See footnote 5.

[10] *Infectious and Lethal Doses of H5N1 Highly Pathogenic Avian Influenza Virus for House Sparrows (Passer Domesticus) and Rock Pigeons (Columbia Livia)* J VET Diagn Invest July 2009 21: 437–445. *Pathogenesis and pathobiology of avian influenza virus infection in birds,* M. J. Pantin-Jackwood and D. E. Swayne, Southeast Poultry Research Laboratory, Agricultural Research Service, USDA, Athens, GA 30605.

[11] World Organization for Animal Health, *Draft Report of the Meeting of the OIE Ad Hoc Group on Avian Influenza,* Paris, 12–14 November 2003.

[12] See footnote 7.

disinfections, and tests as may be required by APHIS to determine their freedom from HPAI and other communicable diseases of poultry. Otherwise, hatching eggs that have originated from any region affected with HPAI will remain prohibited from importation to the United States.

Prohibitions on Birds Vaccinated for Avian Influenza

The interim rule prohibited imports of live poultry that have been vaccinated for H5 or H7 subtypes of avian influenza, as well as imports of day-old chicks and hatching eggs that have been vaccinated or have originated from birds or poultry vaccinated with those subtypes.

Several commenters opposed the import prohibitions we placed on HPAI-vaccinated poultry and hatching eggs.

Two commenters representing the domestic egg industry stated that vaccination for HPAI can be part of an effective disease control program and, for this reason, requested that we reconsider our prohibition on importation of egg layer hatching eggs from vaccinated poultry.

We are making no changes to our prohibition on importation of hatching eggs from poultry vaccinated for HPAI. We noted in the interim rule that vaccination could mask the presence of infection in imported poultry and that vaccinated poultry and hatching eggs would have antibodies to serotypes H5 or H7 detectable during quarantine or routine surveillance. The presence of antibodies in imported poultry and hatching eggs could result in uncertainty as to whether the antibodies originated from vaccination or exposure to HPAI serotypes.

Another commenter stated that diagnostic testing could distinguish antibodies in vaccinated poultry from those acquired from exposure to the HPAI virus, thus eliminating uncertainty as to whether the poultry acquired avian influenza antibodies through vaccination or through natural exposure to the virus.

We are making no changes in response to the comment. We acknowledge that diagnostic methods exist that can distinguish those antibodies created by natural exposure to the virus from those created through vaccination. However, this process, known as DIVA (differentiation of infected from vaccinated animals), has not been sufficiently validated in the field or across avian species.

Another commenter suggested that prohibiting the importation of hatching eggs from vaccinated poultry is unnecessary because embryos infected with lethal strains of HPAI typically die prior to hatching.

We are making no changes based on this information. It is true that transmission of lethal strains of avian influenza via hatching eggs to other birds would be unlikely if the embryos die and fail to hatch. However, broken, contaminated eggs may possibly infect chicks inside the incubator because live virus can be recovered from the eggshell and internal egg contents.

Another commenter opposing the vaccination prohibitions on poultry and hatching eggs noted that other countries sometimes use vaccination to help control H5 and H7 strains of low pathogenic avian influenza (LPAI). The commenter added that APHIS approved use of such vaccines to control a 2002 outbreak of H7N2 LPAI in Virginia.

We are making no changes based on this comment. Emergency vaccination for some avian influenza subtypes may be necessary to control outbreaks if administered under specific conditions and under direct control of veterinary authorities. However, we would not likely allow the export of such emergency vaccinated poultry from the United States, nor would we allow the importation of poultry vaccinated for avian influenza due to the vaccination-related issues discussed above. Only if we were to incorporate the use of vaccinations for H5 and H7 subtypes of avian influenza as routine practice would we reconsider modifying restrictions on the importation of most classes of poultry that have been vaccinated.

Two commenters representing organizations affiliated with U.S. zoos indicated that they import live birds and hatching eggs from throughout the world for the purposes of species preservation and scientific study. They stated that the import prohibition on live birds and hatching eggs vaccinated for avian influenza would adversely affect their ability to import live, zoological birds from other countries. The commenters noted that some foreign zoos already vaccinate zoological birds with avian influenza vaccines as part of their own government programs. The commenters added, however, that their member zoos and other facilities maintain extensive biosecurity and quarantine protocols to ensure that any animal entering their collections is examined and kept in secure facilities to contain any potential disease threat. They stated that, as a result, the risk of introducing HPAI into the United States through such birds is low and asked that we allow importation of zoological birds under such protocols.

We agree with these commenters and are amending 9 CFR 93.104(b)(4) in this final rule to allow live, zoological avians (including some species we define as 'poultry') that have been vaccinated for H5 or H7 subtypes of avian influenza to be imported to approved facilities. In this limited exception, such avians may be imported under specific permit restrictions if they are part of an official program using vaccine products approved and used under the supervision of the veterinary authorities of the exporting country and under specific conditions as determined by the Administrator and included in the import permit. The avians will also be required to be exported with permanent individual identification and meet other certification or entry requirements, including official testing and quarantine on arrival to the United States.

Restrictions on Imports of Bird and Poultry Carcasses, Meat, and Products From Regions Where HPAI Is Considered To Exist

In the interim rule, most of the Newcastle disease-related provisions in 9 CFR 94.6(b) governing importation of bird and poultry carcasses, and parts or products of carcasses, were also applied to importation of those items from regions where HPAI is considered to exist. Historically, nearly all foreign regions where HPAI is considered to exist have also been regions where Newcastle disease has existed, so until the interim rule was published, the provisions for Newcastle disease were being applied *de facto* to HPAI. In the interim rule, we specifically revised those provisions to cover HPAI independent of Newcastle disease. The increasing number of outbreaks of HPAI worldwide has increased the likelihood that the disease could emerge in a region where Newcastle disease has never existed and pose a risk to the United States through the importation of birds, poultry, or bird or poultry products from that region.

While the interim rule specifically applied most of the import provisions for Newcastle disease to HPAI, it did not apply those in 9 CFR 94.6(b)(1) regarding game birds, which state that carcasses of game birds, if eviscerated with heads and feet removed, may be imported from regions where Newcastle disease is considered to exist. We stated in the interim rule that we would consider comments on whether we should apply the same conditions to importation of carcasses of game birds from regions with HPAI.

A commenter stated that the interim rule fails to provide science-based information to show that the restrictions

in the regulations sufficiently mitigate either Newcastle disease or HPAI in game birds. The commenter noted that Newcastle disease virus can be found in all parts of the carcass, and that removal of the head, feet, and viscera is insufficient to prevent introduction of the virus into the United States. The commenter suggested that we remove the Newcastle disease-based game bird provisions from the existing regulations and not extend those provisions to apply to game birds from HPAI regions.

We are making no changes based on the comment. Our experience has shown the disease risk to domestic birds and poultry to be minimal from allowing entry of hunter-harvested carcasses of game birds, intended only for personal consumption and with head, feet, and viscera removed, from regions where Newcastle disease is considered to exist.[13] The number of carcasses imported from such regions historically has been very small and the carcasses are prohibited from entering into commercial channels. However, we continue to evaluate the potential risk to domestic birds and poultry from allowing entry of hunter-harvested carcasses of game birds from regions where HPAI is considered to exist. If we determine that entry of such carcasses from regions with HPAI can occur with sufficient mitigation of risk, we will publish our determination in a future rulemaking. We note that we consider game bird carcasses for personal consumption to be distinct from game bird trophies, which unlike carcasses are allowed entry into the United States from regions affected by HPAI because we require the trophies to be consigned directly under official seal to approved establishments for processing.[14]

An organization representing scientists and others who import ornithological specimens for scientific study opposed our decision to restrict the importation of bird and poultry carcasses, parts, and products from regions where HPAI is considered to exist. The commenter stated that some strains of avian influenza considered to be highly pathogenic based on their molecular characteristics do not present signs of virulence in infected poultry. The commenter suggested that restrictions could be lifted from an HPAI-affected region if diagnostic tests of the avian influenza strain show no signs of virulence.

We are making no changes to this final rule in response to the comment. It is our determination that virulence cannot be adequately ruled out through testing or a lack of observed symptoms in a population of birds or poultry. H5 and H7 strains of avian influenza can have widely varying pathogenic effects on different populations of birds or poultry and are subject to mutations that can change them into virulent strains. However, we note that provisions exist for the importation of ornithological specimens for scientific study. Paragraph (b)(2) of § 94.6 allows carcasses, or parts or products of carcasses, of poultry, game birds, and other birds to be imported for consignment to any museum, educational institution, or other establishment which has provided the Administrator with evidence that it has the equipment, facilities, and capabilities to store, handle, process, or disinfect such articles so as to prevent the introduction or dissemination of Newcastle disease or HPAI into the United States, and which is approved by the Administrator.

A consumer safety organization objected to the interim rule, stating that it was concerned that the rule lifts import restrictions APHIS had placed on all poultry products from regions where HPAI is considered to exist, particularly the People's Republic of China.

The interim rule did not lift import restrictions on poultry products from any region where HPAI is considered to exist. On the contrary, the interim rule applied the restrictions in 9 CFR 94.6(b) for unprocessed carcasses and parts or products of unprocessed carcasses of poultry or other birds from regions where Newcastle disease is considered to exist to regions where HPAI is considered to exist. These items are not eligible for import except when deemed appropriate by APHIS for scientific, educational, or research purposes, and must undergo processing conditions that ensure destruction of these viruses, if present. Carcasses of poultry or other birds that originated in a region considered to be free of Newcastle disease and HPAI, but that are processed (cut, packaged, or other processing) in a region where Newcastle disease or HPAI is considered to exist, are only eligible for import if they have been cooked or otherwise processed in such a way as to ensure destruction of Newcastle disease and avian influenza viruses, and if the processing establishments from which they come satisfy all the requirements in 9 CFR 94.6(b)(5). In deciding whether to approve a processing establishment, we determine the establishment's compliance with APHIS animal health requirements and the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) evaluates the exporting region's processing methods for products for human consumption under the Poultry Products Inspection Act. If the processing establishments of any country or region do not meet both APHIS and FSIS requirements, those establishments are not permitted to export bird and poultry meat and products to the United States.

Cooking and Egg Pasteurization Requirements

Prior to the interim rule, we required in 9 CFR 94.6(b) that cooked carcasses, parts, or products of poultry or other birds from regions considered to have Newcastle disease ''have a thoroughly cooked appearance throughout.'' Based on our review of OIE recommendations, we revised our cooking requirements to be more effective against both HPAI and Newcastle disease viruses. Accordingly, in the interim rule, we amended 9 CFR 94.6(b)(4) to establish a single standard stating that the articles must be cooked to a minimum internal temperature throughout of 74 °C (165 °F). This requirement replaced the previous standard that required confirmation by an inspector that the poultry appeared to be thoroughly cooked.

Four commenters disagreed with our establishment of a single cooking standard. One stated that application of any of the appropriate OIE cooking standards will result in products with negligible disease risk. Another commenter agreed, adding that cooking with the intention of eliminating avian influenza viruses is dependent on both cooking temperature and time. Another commenter noted that there may be certain products where heating to 74 °C is not sufficient and that for those products additional cooking standards might need to be considered. A commenter also requested that APHIS apply the cooking requirement only to imported bird and poultry products intended for consumption and not to products imported for scientific purposes, which have their own heat treatment requirements.

The cooking regulations we established in the interim rule are intended to simplify the cooking

[13] Importation of such carcasses is also subject to verification of the import documentation by a U.S. Fish and Wildlife Service (FWS) officer. Information on FWS requirements for bringing game birds can be found at: *http://www.fws.gov/le/hunting.html*.

[14] Requirements for importing bird trophies from regions where Newcastle disease or HPAI is considered to exist are addressed in 9 CFR 95.17. Such trophies do not require an import permit but are required to be moved under official seal to approved establishments. Entry requirements for bird trophies imported from regions free of Newcastle disease and HPAI are addressed in 9 CFR 95.16.

process by mitigating the risks of HPAI and Newcastle disease viruses in cooked poultry products under a single standard. We have determined that a cooking temperature of 74 °C is sufficient to mitigate both viruses. If we determine that the regulations need to be amended to allow alternative processing standards in products intended for consumption or scientific purposes, we will consider that change in a future rulemaking. We will also consider alternative cooking and heat treatment approaches that are scientifically supportable and meet international standards. We will work with industry and researchers to validate other standards and welcome specific information to help us develop such standards. We will also harmonize procedures with FSIS to verify that their public health standards are also suitable for inactivating HPAI and Newcastle disease viruses.

Two commenters asked that we also include OIE egg pasteurization standards in the regulations.

We do not consider it necessary to include such standards in the regulations. As with poultry meat and products, APHIS currently applies international standards for egg products that are validated by USDA researchers and harmonizes its procedures with FSIS whenever possible.

Cooked Poultry Meat in Passenger Baggage

One commenter noted that the changes to the interim rule do not provide clear guidance on the importation requirements for cooked poultry meat entering the United States in passenger baggage. The commenter stated that if APHIS intends to apply the cooking requirement that we included in the interim rule, then we should specify whether this requirement applies only to commercially imported poultry meat and poultry products, including table eggs, or whether it also extends to cooked poultry meat in passenger baggage.

On the same subject, another commenter disagreed with how we implemented the change in the interim rule to the cooking regulations, which requires official certification stating that the proper cooking temperature had been applied to accompany all cooked carcasses, parts, or products of poultry or other birds entering the United States from regions where Newcastle disease or HPAI is considered to exist. The commenter stated that we did not adequately inform Department of Homeland Security, Customs Border and Protection (CBP) inspectors or the traveling public about this change, resulting in disruptions at ports of entry as CBP officials were not adequately prepared to manage the large quantity of uncertified cooked poultry meat and eggs seized in passenger baggage as a result of enforcement of the interim rule. To address this situation, a commenter representing an international restaurant chain requested that we amend the cooking regulations in 9 CFR 94.6(b)(6) to include an exception for perishable cooked poultry products intended for personal consumption in passenger baggage.

After we published the new cooking regulations, we recognized that it was impractical to require passengers entering the country to produce a cooking certificate for non-commercial quantities of perishable, thoroughly cooked poultry intended for personal consumption. We determined from experience that such importations pose an insignificant risk to domestic birds and poultry. Accordingly, we published in the APHIS Animal Products Manual a directive [15] that CBP inspectors may permit entry of cooked and perishable poultry products for personal consumption if, in the view of the inspector, the products appear to be thoroughly cooked throughout. If the products do not appear in the inspector's determination to be thoroughly cooked or intended for personal consumption, entry of the product will be denied. We believe that this directive is reliable since we allow inspectors in other cases to draw on their experience and judgment to determine whether a product is sufficiently processed to minimize risk. Accordingly, we will proceed with this directive but we plan to include this exception for cooked poultry in the regulations in the future.

Table Eggs From Regions Where HPAI Is Considered To Exist

One commenter noted that while the interim rule clearly explained how we changed the regulations for importing poultry products and byproducts from regions where HPAI is considered to exist, the regulations provide no clear guidance as to whether this change applies to table eggs and egg products (other than hatching eggs) from such regions.

In the interim rule, we made no changes to 9 CFR 94.6(c), which lists import requirements for table eggs from regions where Newcastle disease is considered to exist. We solicited comments in the interim rule on whether a targeted testing program for HPAI in egg flocks in foreign regions is advisable and how such a program might be designed to provide a statistically valid testing regimen. We noted that those who wish to comment on this issue should also review a final rule we published in the **Federal Register** on April 22, 2009 (''Importation of Table Eggs From Regions Where Exotic Newcastle Disease Exists,'' Docket No. APHIS–2007–0014; 74 FR 18285–18288). That document amended 9 CFR 94.6(c) to include a protocol for targeted Newcastle disease testing of a statistically valid sample of dead, dying, and cull birds. It would also be possible to create such a targeted testing program for HPAI, although the sample sizes, type of tests, and other technical details would vary. In the future, we intend to use the same process to develop regulations for importation of table eggs from HPAI regions, beginning with a risk assessment that reviews the testing options. This assessment would be made available for public comment.

However, we are adding language to § 94.6 (c) to clarify that table eggs from HPAI regions are prohibited from importation, except by APHIS permit to approved establishments for breaking and pasteurization, for scientific, educational, or research purposes, or for other purposes determined by the Administrator, provided that the eggs have been cooked, processed, or otherwise handled in a manner that will prevent the introduction of both Newcastle disease and HPAI into the United States.

Three commenters recommended that APHIS consider adopting provisions of the Secure Egg Supply (SES) plan for imports of poultry and egg products to the United States, and one commenter recommended that we modify 9 CFR 94.6(c) to require exporting countries to implement systems equivalent to the SES plan as a condition for continuing exports to the United States should those countries have HPAI outbreaks. The SES plan implements levels of heightened biosecurity, additional testing, and other emergency measures during a disease outbreak.

We believe that the adoption of such broad emergency measures in this context is not necessary. Incorporating provisions of the SES plan into general guidance under normal trade conditions is unnecessary and would be potentially burdensome to domestic egg producers.

Additional Treatments for Research Specimens

A commenter interested in the scientific study of birds asked that we

[15] *http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/apm.pdf.* See footnote 1, Table A–1–10.

make it easier to access approved treatment methods that are currently established as conditions for obtaining an import permit and requested that we make such information available on the APHIS Web site.

For specific information regarding approved treatment methods, please contact National Import Export Services at (301) 851–3300, or send an email to *AskNCIE.Products@aphis.usda.gov.* A search engine listing approved establishments where such treatment methods are administered is available online at: *https://vsapps.aphis.usda.gov/vsps/public/AESearch.do?method=unspecified.*

The same commenter requested that we also consider another process for importing untreated material of avian origin, noting that current treatment requirements somewhat degrade materials intended for research and asked that we consider establishing a procedure for pre-import testing of the material in a laboratory and with methods equivalent to those used by USDA labs.

We welcome scientific information that supports other processes for testing, handling, and importing untreated avian material in such a manner that minimizes the risk of introducing HPAI or other avian diseases. Other procedures will be considered in the future on a case-by-case basis.

Regionalization

Two commenters, including an official representing the EU, stated that APHIS uses the term ''region'' to refer only to the whole territory of a country and not to a part of a country, and recommended that we include regionalization as part of our regulations to be in line with OIE recommendations.

We currently recognize regions that span countries and parts of countries for animal disease control purposes and which are based on geographic considerations instead of national boundaries, as recommended by the OIE. In the past, APHIS has removed from that list several subnational regions consisting of either single or several administrative units or groups within the EU that were affected by HPAI H5N1.[16]

Disease Terms

A commenter questioned our use of the term ''exotic'' in conjunction with ''Newcastle disease,'' noting that it does not conform to OIE usage, and also requested that we replace the term ''European fowl plague'' with ''highly pathogenic avian influenza'' in our regulations, noting that the latter term is more in line with international usage.

APHIS agrees with the commenter's suggestions. In another rulemaking,[17] we have since removed the word ''exotic'' from references to Newcastle disease and replaced the terms ''fowl pest'' and ''fowl plague'' with ''highly pathogenic avian influenza.'' The word ''exotic'' is no longer a useful description of Newcastle disease, and the terms ''fowl pest'' and ''fowl plague'' predate identification of the avian influenza virus and are no longer commonly used in scientific discourse. This change is consistent with our previous efforts to replace these outdated terms in other parts of our regulations and reflects OIE terminology.

Other Changes

We are making other changes to the regulations to provide readers with additional information about terms we use in the regulations. We are adding a definition of *approved establishment* to 9 CFR 94.0. This term refers to establishments authorized by APHIS for the receipt and handling of restricted imported animal carcasses, trophies, products, and byproducts. We are adding this term in order to distinguish such establishments from ''processing establishments'' that process meat, fish, and poultry intended for human consumption. We are also adding a definition of *commercial birds* to 9 CFR 94.0 in order to distinguish birds imported for resale, breeding, public display, or any other purpose from birds imported for zoological or research purposes, performing or theatrical purposes, and as pets. In addition, we are adding a similar definition for *commercial poultry* to 9 CFR 93.200 and 94.0 to distinguish such poultry from other types recognized in the regulations. We are also revising the definition of *highly pathogenic avian influenza* in 9 CFR 94.0 to harmonize it with OIE standards and adding that definition to 9 CFR 93.100, 93.200, and 95.1, as we now use that term in those regulations. We are adding a definition of *quarantine facility* to 9 CFR 93.100 of Subpart A—Birds and 9 CFR 93.200 of Subpart B—Poultry because we include requirements for quarantine facilities in those subparts but provide no definition of the term.

We are also amending the list of disease agents (anthrax, foot-and-mouth disease, and rinderpest) in 9 CFR 95.3 to clarify that importation of byproducts taken or removed from any animal affected with Newcastle disease or HPAI are specifically prohibited. Under amended 9 CFR 95.17 we will allow products such as bird trophies from HPAI regions to be consigned directly to an approved establishment, as is currently the case with bird trophies from regions with Newcastle disease. Such trophies consigned directly to an approved establishment do not require an import permit. Therefore, we are removing 9 CFR 95.41 from the regulations because the import permit required in that section specifically for bird trophies from HPAI regions is no longer necessary.

Finally, we are correcting an incorrect reference in § 94.6. Currently, paragraph (c)(3) states the requirements for the importation of eggs for scientific, educational, or research purposes and that the eggs must be accompanied by a permit obtained from APHIS in accordance with paragraph (f) of that section. Paragraph (f) was removed in a prior rulemaking and the instructions for obtaining a permit are currently contained in paragraph (d). We are correcting that reference.

Addition of Bhutan to the List of Regions in Which HPAI Is Considered To Exist

We are also announcing that we have added Bhutan to the list of regions referenced in 9 CFR 94.6(a)(2)(i) in which HPAI is considered to exist because we have determined that HPAI exists in commercial birds or poultry in the country based on veterinary reports of disease outbreaks.

Therefore, for the reasons given in the interim rule and in this document, we are adopting the interim rule as a final rule, with the changes discussed in this document.

Effective Date

Pursuant to the administrative procedure provisions in 5 U.S.C. 553, we find good cause for making this rule effective less than 30 days after publication in the **Federal Register**. The interim rule adopted as final by this rule became effective on January 24, 2011. This rule relieves a restriction in the interim rule that prohibits the import of birds vaccinated for avian influenza subtypes H5 or H7 by permitting the import of vaccinated zoological birds to approved facilities under controlled conditions. This rule also relieves a restriction that prohibits the importation of HPAI-resistant pigeons, doves, and other Columbiform species by permitting the import of such species,

[16] The subnational regions removed include areas within Denmark and France (July 21, 2008); Germany (June 5, 2009 and September 23, 2009); Poland (June 5, 2009); United Kingdom (September 23, 2009); Hungary (September 24, 2009); and the Czech Republic and Sweden (November 10, 2010).

[17] See footnote 7.

under permit and controlled conditions, from regions where HPAI is considered to exist. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective upon publication in the **Federal Register**.

Executive Order 12866 and Regulatory Flexibility Act

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

We have prepared an economic analysis for this rule. The economic analysis, which is summarized below, examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

To prevent the introduction of HPAI into the United States, APHIS published an interim rule that amended the regulations in 9 CFR parts 93, 94, and 95 to prohibit or restrict the importation of birds and poultry products from regions where HPAI exists. APHIS is adopting the rule with changes: The final rule will allow the importation of live zoological birds vaccinated for HPAI under controlled conditions to approved facilities and allow the importation of pigeons, doves, and other Columbiform species resistant to HPAI under permit and controlled conditions from regions where HPAI is considered to exist.

Because of the substantial overlap between existing restrictions to prevent the importation of articles that could introduce Newcastle disease and the new restrictions to prevent the importation of articles that could introduce HPAI, this final rule is not expected to have significant economic impacts on small entities. The rule will benefit U.S. poultry and egg producers by protecting domestic flocks against the introduction of HPAI. Consumers and importers will not be significantly affected by any changes in imports that may result because of the rule, as poultry and poultry product imports are minor compared to domestic production. Compliance costs will be incurred only with respect to imports from regions where HPAI is discovered and there are no existing restrictions for HPAI or Newcastle disease.

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

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Has no retroactive effect and (2) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0245 (formerly 0579–0367).

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 rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

List of Subjects

9 CFR Part 93

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

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 95

Animal feeds, Hay, Imports, Livestock, Reporting and recordkeeping requirements, Straw, Transportation.

Accordingly, the interim rule amending 9 CFR parts 93, 94, and 95 that was published at 76 FR 4046–4056 on January 24, 2011, is adopted as a final rule with the following changes:

PART 93–IMPORTATION OF CERTAIN ANIMALS, BIRDS, FISH, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 93.100 is amended by adding, in alphabetical order, definitions of *highly pathogenic avian influenza (HPAI)* and *quarantine facility* to read as follows:

§ 93.100 Definitions.

* * * * *

Highly pathogenic avian influenza (HPAI). Highly pathogenic avian influenza is defined as follows:

(1) Any influenza virus that kills at least 75 percent of eight 4- to 6-week-old susceptible chickens within 10 days following intravenous inoculation with 0.2 mL of a 1:10 dilution of a bacteria-free, infectious allantoic fluid or inoculation of 10 susceptible 4- to 8-week-old chickens resulting in an intravenous pathogenicity index (IVPI) of greater than 1.2;

(2) Any H5 or H7 virus that does not meet the criteria in paragraph (1) of this definition, but has an amino acid sequence at the haemagglutinin cleavage site that is compatible with highly pathogenic avian influenza viruses; or

(3) Any influenza virus that is not an H5 or H7 subtype and that kills one to five out of eight inoculated chickens and grows in cell culture in the absence of trypsin within 10 days.

* * * * *

Quarantine facility. A USDA facility, or a private facility approved by APHIS, for the secure housing of imported birds, poultry, or other animals for specified periods.

* * * * *

■ 3. Section 93.101 is amended as follows:

■ a. In paragraph (a), by revising the last sentence;

■ b. In paragraph (c)(4)(i), by adding the words ''highly pathogenic avian influenza,'' before the words ''Newcastle disease'';

■ c. In paragraph (g)(2), by adding the words ''highly pathogenic avian influenza and'' before the words ''Newcastle disease'';

■ d. By revising footnote 7;

■ e. In paragraph (g)(3), by adding the words ''highly pathogenic avian influenza and'' before the words

''Newcastle disease'' the first and second time they appear, and by adding the words ''highly pathogenic avian influenza or'' before the words ''Newcastle disease'' the third and fourth time they appear; and

■ f. In paragraph (g)(4), by adding the words ''highly pathogenic avian influenza and'' before the words ''Newcastle disease''.

The revisions read as follows:

§ 93.101 General prohibitions; exceptions.

(a) * * * Unless otherwise indicated in the regulations, no live birds, and no hatching eggs from birds, shall be imported into the United States if the birds have originated from a region referenced in § 94.6(a) of this subchapter where highly pathogenic avian influenza or Newcastle disease is known to exist in commercial poultry populations, have transited highly pathogenic avian influenza- or Newcastle disease-affected regions, or have been vaccinated for the H5 or H7 subtype of avian influenza.

* * * * *

[7] Such tests are conducted according to protocols for highly pathogenic avian influenza and Newcastle disease which are available upon request from the Administrator.

■ 4. Section 93.104 is amended as follows:

■ a. In paragraphs (b)(2) and (b)(3), by adding the words ''highly pathogenic avian influenza,'' before the word ''chlamydiosis'';

■ b. By revising paragraph (b)(4);

■ c. In paragraph (b)(5), by adding the words ''highly pathogenic avian influenza or'' before the words ''Newcastle disease'';

■ d. In paragraph (b)(6), by adding the words ''originated from or'' before the words ''been moved through a region identified in accordance with § 94.6(a) of this subchapter as a region where highly pathogenic avian influenza exists;'';

■ e. In paragraph (b)(7), by removing the words ''previously unused containers'' and adding the words ''new or appropriately sanitized packaging materials'' in their place;

■ f. In paragraphs (c)(3) and (c)(4), by adding the words ''highly pathogenic avian influenza,'' before the word ''chlamydiosis'';

■ g. In paragraph (c)(6), by adding the words ''highly pathogenic avian influenza or'' before the words ''Newcastle disease'';

■ h. In paragraph (c)(7), by adding the words ''originated from or'' before the words ''been moved through a region identified in accordance with § 94.6(a) of this subchapter as a region where highly pathogenic avian influenza exists;'';

■ i. In paragraph (c)(11), by removing the words ''previously unused containers'' and adding the words ''new or appropriately sanitized packaging materials'' in their place;

■ j. In paragraphs (d)(3) and (d)(4), by adding the words ''highly pathogenic avian influenza,'' before the word ''chlamydiosis'';

■ k. In paragraph (d)(5), by adding the words ''highly pathogenic avian influenza or'' before the words ''Newcastle disease''; and

■ l. In paragraph (d)(7), by removing the words ''previously unused containers'' and adding the words ''new or appropriately sanitized packaging materials'' in their place.

The revision reads as follows:

§ 93.104 Certificate for pet birds, commercial birds, zoological birds, and research birds.

* * * * *

(b) * * *

(4) That the birds have not been vaccinated with a vaccine for the H5 or H7 subtype of avian influenza; however, zoological birds that have been vaccinated for avian influenza subtypes H5 or H7 as part of an official program, using vaccine products approved and used under supervision by the veterinary authorities of the exporting country, may be imported under specific conditions as determined by the Administrator and specified in an import permit. Such birds must be exported with permanent individual identification and meet the other requirements for entry under this part, and will be subject to official testing and quarantine on arrival to the United States.

* * * * *

■ 5. Section 93.106 is amended as follows:

■ a. In paragraph (b)(3), by adding the words ''highly pathogenic avian influenza and'' before the words ''Newcastle disease'';

■ b. In paragraph (c)(3)(ii)(E), by revising the last sentence;

■ c. In paragraphs (c)(5)(iii)(A)(14) and (c)(5)(iii)(A)(17), by adding the words ''highly pathogenic avian influenza or'' before the words ''Newcastle disease''; and

■ d. In paragraphs (c)(5)(iii)(B)(4) and (c)(5)(iii)(B)(5), by adding the words ''highly pathogenic avian influenza or'' before the words ''Newcastle disease''.

The revision reads as follows:

§ 93.106 Quarantine requirements.

* * * * *

(c) * * *

(3) * * *

(ii) * * *

(E) * * * If Newcastle disease or highly pathogenic avian influenza is found or detected among any birds in quarantine, all birds in the facility shall be destroyed or refused entry and the entire facility shall be thoroughly cleaned and then disinfected as directed under the supervision of an inspector.

* * * * *

■ 6. Section 93.200 is amended by adding, in alphabetical order, definitions of *commercial poultry, highly pathogenic avian influenza (HPAI),* and *quarantine facility* to read as follows:

§ 93.200 Definitions.

* * * * *

Commercial poultry. Chickens, doves, ducks, geese, grouse, guinea fowl, partridges, pea fowl, pheasants, pigeons, quail, swans, and turkeys (including eggs for hatching) which are imported for resale, breeding, public display, or any other commercial purpose.

* * * * *

Highly pathogenic avian influenza (HPAI). Highly pathogenic avian influenza is defined as follows:

(1) Any influenza virus that kills at least 75 percent of eight 4- to 6-week-old susceptible chickens within 10 days following intravenous inoculation with 0.2 mL of a 1:10 dilution of a bacteria-free, infectious allantoic fluid or inoculation of 10 susceptible 4- to 8-week-old chickens resulting in an intravenous pathogenicity index (IVPI) of greater than 1.2;

(2) Any H5 or H7 virus that does not meet the criteria in paragraph (1) of this definition, but has an amino acid sequence at the haemagglutinin cleavage site that is compatible with highly pathogenic avian influenza viruses; or

(3) Any influenza virus that is not an H5 or H7 subtype and that kills one to five out of eight inoculated chickens and grows in cell culture in the absence of trypsin within 10 days.

* * * * *

Quarantine facility. A USDA facility, or a private facility approved by APHIS, for the secure housing of imported birds, poultry, or other animals for specified periods.

* * * * *

■ 7. Section 93.201 is amended as follows:

■ a. In paragraph (a), by revising the last sentence of the paragraph; and

■ b. By adding paragraph (e).

The revision and addition read as follows:

§ 93.201 General prohibitions; exceptions.

(a) * * * Unless otherwise indicated in the regulations, no live poultry, and no hatching eggs from poultry, shall be imported into the United States if the poultry have originated from a region referenced in § 94.6(a) of this subchapter where highly pathogenic avian influenza or Newcastle disease is known to exist in commercial poultry populations, have transited highly pathogenic avian influenza- or Newcastle disease-affected regions, or have been vaccinated for the H5 or H7 subtype of avian influenza.

* * * * *

(e) Pigeons, doves, and other Columbiform species that have originated from or transited regions where highly pathogenic avian influenza is considered to exist may be imported into the United States under permit and controlled conditions to approved establishments subject to all applicable requirements in this part.

* * * * *

■ 8. Paragraphs (a) and (b) of § 93.205 are revised to read as follows:

§ 93.205 Certificate for live poultry and hatching eggs.

(a) *Live poultry.* (1) All live poultry, except eggs for hatching, offered for importation from any region of the world shall be accompanied by a certificate stating that such poultry and their flock or flocks of origin were inspected on the premises of origin immediately before the date of movement from such region and that they were then found to be free of evidence of communicable diseases of poultry. The certificate shall also state that, as far as it has been possible to determine, during the 90 days prior to movement, the poultry were not exposed to communicable diseases of poultry and the premises were not in any area under quarantine. The certificate shall also state that the poultry have not been vaccinated with a vaccine for the H5 or H7 subtype of avian influenza. The certificate shall also state that the poultry have been kept in the region from which they are offered for importation since they were hatched, or for at least 90 days immediately preceding the date of movement, that the poultry have not originated from or have been moved through a region referenced in § 94.6(a) of this subchapter as a region where any form of highly pathogenic influenza exists, and that, as far as it has been possible to determine, no case of highly pathogenic avian influenza or Newcastle disease occurred on the premises where such poultry were kept, or on adjoining premises, during that 90-day period. The certificate must also state that the birds were placed into new or appropriately sanitized packaging materials at the premises from which the birds were to be exported.

(2) Live poultry certificates accompanying pigeons, doves, and other Columbiform species that have originated from or been moved through regions where highly pathogenic avian influenza is considered to exist must additionally state that the Columbiform species have been moved and handled under conditions specified on the import permit ensuring that their movement and handling involved no direct or indirect exposure to other animals, birds, and poultry.

(b) *Hatching eggs.* All eggs for hatching offered for importation from any part of the world shall be accompanied by a certificate stating that the flock or flocks of origin were found upon inspection to be free from evidence of communicable diseases of poultry, the hatching eggs are from poultry that have not been vaccinated with a vaccine for the H5 or H7 subtype of avian influenza, that during the 90 days prior to movement, the flock or flocks of origin were not exposed to communicable diseases of poultry and the premises were not in any area under quarantine, and that the hatching eggs and the flock or flocks of origin have not originated in or been moved through a region referenced in accordance with § 94.6(a) of this subchapter as a region where any form of highly pathogenic avian influenza exists. The certificate must also state that the hatching eggs were placed into new or appropriately sanitized packaging materials at the premises from which the hatching eggs were to be exported.

* * * * *

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, NEWCASTLE DISEASE, HIGHLY PATHOGENIC AVIAN INFLUENZA, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, SWINE VESICULAR DISEASE, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 9. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 10. Section 94.0 is amended as follows:

■ a. By adding, in alphabetical order, definitions of *approved establishment, commercial birds,* and *commercial poultry;* and

■ b. By revising the definition of *highly pathogenic avian influenza.*

The additions and revision read as follows:

§ 94.0 Definitions.

* * * * *

Approved establishment means an establishment authorized by Veterinary Services for the receipt and handling of restricted imported animal carcasses, products, and byproducts.

* * * * *

Commercial birds. Birds that are imported for resale, breeding, public display, or any other purpose, except pet birds, zoological birds, research birds, or performing or theatrical birds.

Commercial poultry. Chickens, doves, ducks, geese, grouse, guinea fowl, partridges, pea fowl, pheasants, pigeons, quail, swans, and turkeys (including eggs for hatching) which are imported for resale, breeding, public display, or any other commercial purpose.

* * * * *

Highly pathogenic avian influenza (HPAI). Highly pathogenic avian influenza is defined as follows:

(1) Any influenza virus that kills at least 75 percent of eight 4- to 6-week-old susceptible chickens within 10 days following intravenous inoculation with 0.2 mL of a 1:10 dilution of a bacteria-free, infectious allantoic fluid or inoculation of 10 susceptible 4- to 8-week-old chickens resulting in an intravenous pathogenicity index (IVPI) of greater than 1.2;

(2) Any H5 or H7 virus that does not meet the criteria in paragraph (1) of this definition, but has an amino acid sequence at the haemagglutinin cleavage site that is compatible with highly pathogenic avian influenza viruses; or

(3) Any influenza virus that is not an H5 or H7 subtype and that kills one to five out of eight inoculated chickens and grows in cell culture in the absence of trypsin within 10 days.

* * * * *

■ 11. Section 94.6 is amended as follows:

■ a. By revising paragraph (a)(1)(i);

■ b. In paragraph (a)(1)(ii), in the first sentence, by adding the word ''referenced'' after the word ''list'';

■ c. In paragraph (b)(2), by adding the words ''from regions where Newcastle disease or HPAI are considered to exist'' after the words ''and other birds'';

■ d. In the heading and introductory text of paragraph (c), by adding the words ''or HPAI'' after the words ''Newcastle disease'' each time they occur;

■ e. In paragraphs (c)(1)(ix) introductory text, (c)(1)(ix)(A), and (c)(1)(ix)(B), by adding the words ''or HPAI'' after the words ''Newcastle disease'' each time they occur;
■ f. In paragraph (c)(1)(ix)(C), in the first sentence, by adding the words ''region free of HPAI, or from a'' before the words ''flock of origin'';
■ g. In paragraph (c)(2), by adding the words ''and HPAI'' after the words ''Newcastle disease'';
■ h. In paragraph (c)(3), by adding the words ''and HPAI'' after the words ''Newcastle disease'' each time they occur, and by removing the words ''paragraph (f)'' and adding the words ''paragraph (d)'' in their place; and
■ i. In paragraph (c)(4), by removing the words ''paragraph (f)'' and adding the words ''paragraph (d)'' in their place.

The revision reads as follows:

§ 94.6 Carcasses, meat, parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, or other birds; importations from regions where Newcastle disease or highly pathogenic avian influenza is considered to exist.

(a) * * *
(1) * * *
(i) A list of such regions is maintained on the APHIS National Import Export Services Web site at *http://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml.* Copies of the list will also be available upon request to Regional Evaluation Services, National Import Export Services, Veterinary Services, Animal and Plant Health Inspection Service, 4700 River Road Unit 38, Riverdale, Maryland 20737; fax: (301) 851–3300; email: *AskNCIE.Products@aphis.usda.gov.*
* * * * *

PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES

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

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

■ 13. Section 95.1 is amended by adding, in alphabetical order, the definition of *highly pathogenic avian influenza (HPAI)* to read as follows:

§ 95.1 Definitions.

* * * * *

Highly pathogenic avian influenza (HPAI). Highly pathogenic avian influenza is defined as follows:

(1) Any influenza virus that kills at least 75 percent of eight 4- to 6-week-old susceptible chickens within 10 days following intravenous inoculation with 0.2 mL of a 1:10 dilution of a bacteria-free, infectious allantoic fluid or inoculation of 10 susceptible 4- to 8-week-old chickens resulting in an intravenous pathogenicity index (IVPI) of greater than 1.2;

(2) Any H5 or H7 virus that does not meet the criteria in paragraph (1) of this definition, but has an amino acid sequence at the haemagglutinin cleavage site that is compatible with highly pathogenic avian influenza viruses; or

(3) Any influenza virus that is not an H5 or H7 subtype and that kills one to five out of eight inoculated chickens and grows in cell culture in the absence of trypsin within 10 days.

* * * * *

§ 95.3 [Amended]

■ 14. Section 95.3 is amended by adding the words ''highly pathogenic avian influenza, Newcastle disease,'' after the words ''foot-and-mouth disease,''.

§ 95.16 [Amended]

■ 15. Section 95.16 is amended as follows:

■ a. In the introductory text, by removing the citation ''§ 95.6'' and adding the citation ''§ 95.17'' in its place; and

■ b. In footnote 1, by removing the citation ''§ 95.41'' and adding the citation ''§ 95.17'' in its place.

§ 95.17 [Amended]

■ 16. In § 95.17, paragraph (c) is amended by adding the word ''highly pathogenic avian influenza,'' after the words ''African swine fever,''.

§ 95.23 [Amended]

■ 17. In § 95.23, paragraph (c) is amended by removing the word ''and'' after the words ''foot-and-mouth disease,'' and by adding the words ''highly pathogenic avian influenza, and Newcastle disease,'' after the word ''rinderpest,''.

§ 95.41 [Removed]

■ 18. Section 95.41 is removed.

Done in Washington, DC, this 25th day of November 2014.

Jere L. Dick,

Associate Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–28244 Filed 11–28–14; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. FSIS–2014–0042]

RIN 0583–AD05

Uniform Compliance Date for Food Labeling Regulations

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is establishing January 1, 2018, as the uniform compliance date for new meat and poultry product labeling regulations that are issued between January 1, 2015, and December 31, 2016. FSIS periodically announces uniform compliance dates for new meat and poultry product labeling regulations to minimize the economic impact of label changes.

DATES: This rule is effective December 1, 2014. Comments on this final rule must be received on or before December 31, 2014.

ADDRESSES: FSIS invites interested persons to submit relevant comments on this final rule. Comments may be submitted by the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov/.* Follow the online instructions at that site for submitting comments.
- Mail, including CD–ROMs: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, OPPD, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8–163A, Washington, DC 20250–3700.
- Hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, OPPD, Patriots Plaza 3, 355 E Street SW., Room 8–163A, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2014–0042. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov/.*

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 8–164, Washington, DC 20250–3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Rosalyn Murphy-Jenkins, Director, Labeling and Program Delivery Division, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Telephone: 301–504–0879.

SUPPLEMENTARY INFORMATION:

Background

FSIS periodically issues regulations that require changes in the labeling of meat and poultry food products. Many meat and poultry establishments also produce non-meat and non-poultry food products that are subject to the jurisdiction of the Food and Drug Administration (FDA). FDA also periodically issues regulations that require changes in the labeling of products under its jurisdiction.

On December 14, 2004, FSIS issued a final rule that established January 1, 2008, as the uniform compliance date for new meat and poultry labeling regulations issued between January 1, 2005, and December 31, 2006. The 2004 final rule also provided that the Agency would set uniform compliance dates for new labeling regulations in 2-year increments and periodically issue final rules announcing those dates. Consistent with that final rule, the Agency has published four final rules establishing the uniform compliance dates of January 1, 2010, January 1, 2012, January 1, 2014, and January 1, 2016 (72 FR 9651, 73 FR 75564, 75 FR 71344, and 77 FR 76824).

The Final Rule

This final rule establishes January 1, 2018, as the uniform compliance date for new meat and poultry product labeling regulations that are issued between January 1, 2015 and December 31, 2016, and is consistent with the previous final rules that established uniform compliance dates. In addition, FSIS's approach for establishing uniform compliance dates for new food labeling regulations is consistent with FDA's approach. FDA is also planning to publish a final rule establishing a new compliance date.

Two-year increments enhance the industry's ability to make orderly adjustments to new labeling requirements without unduly exposing consumers to outdated labels. With this approach, the meat and poultry industry is able to plan for use of label inventories and to develop new labeling materials that meet the requirements of all labeling regulations made within the two year period, thereby minimizing the economic impact of labeling changes.

This compliance approach also serves consumer's interests because the cost of multiple short-term label revisions that would otherwise occur would likely be passed on to consumers in the form of higher prices.

FSIS encourages meat and poultry companies to comply with new labeling regulations as soon as it is feasible. If companies initiate voluntary label changes, they should consider incorporating any new requirements that have been published as final regulations.

The new uniform compliance date will apply only to final FSIS regulations that require changes in the labeling of meat and poultry products and that are published after January 1, 2015, and before December 31, 2016. For each final rule that requires changes in labeling, FSIS will specifically identify January 1, 2018, as the compliance date. All meat and poultry food products that are subject to labeling regulations promulgated between January 1, 2015 and December 31, 2016, will be required to comply with these regulations on products introduced into commerce on or after January 1, 2018. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2018, the Agency will determine an appropriate compliance date and will publish that compliance date in the rulemaking.

In rulemaking that began with the May 4, 2004, proposed rule, FSIS provided notice and solicited comment on the concept of establishing uniform compliance dates for labeling requirements (69 FR 24539). In the March 5, 2007, final rule, FSIS noted that the Agency received only four comments in response to the proposal, all fully supportive of the policy to set uniform compliance dates. Therefore, in the March 5, 2007, final rule, FSIS determined that further rulemaking for the establishment of uniform compliance dates for labeling requirements is unnecessary (72 FR 9651). The Agency did not receive comments on the 2007 final rule, and the comments FSIS received on the 2012 final rule on the uniform compliance date were outside the scope of the rule (77 FR 76824). Consistent with its statement in 2007, FSIS finds at this time that further rulemaking on this matter is unnecessary. However, FSIS is providing an opportunity for comment on the uniform compliance date established in this final rule.

Executive Order 12988

This final rule has been reviewed under the Executive Order 12988, Civil Justice Reform. Under this final rule: (1) All state and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no retroactive proceedings will be required before parties may file suit in court challenging this rule.

Executive Orders 12866 and 13563 and the Regulatory Flexibility Act

Executive Orders 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). Executive Order (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 has been reviewed under E.O. 12866. The Office of Management and Budget (OMB) has determined that it is a not significant regulatory action under section 3(f) of E.O. 12866 and, therefore, it has not been reviewed by OMB.

This rule does not have a significant economic impact on a substantial number of small entities; consequently, a regulatory flexibility analysis is not required (5 U.S.C. 601–612).

Paperwork Requirements

There are no paperwork or recordkeeping requirements associated with this policy under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

E-Government Act Compliance

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

USDA Nondiscrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail

U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410

Fax

(202) 690–7442

Email

program.intake@usda.gov

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Additional Public Notification

FSIS will announce this rule online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/Interim_&_Final_Rules/index.asp.*

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/News_&_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 accounts.

Done at Washington, DC on: November 25, 2014

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2014–28269 Filed 11–28–14; 8:45 am]

BILLING CODE 3410–DM–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

10 CFR Part 1708

Procedures for Safety Investigations

AGENCY: Defense Nuclear Facilities Safety Board.

ACTION: Final rule.

SUMMARY: The Defense Nuclear Facilities Safety Board (Board) is promulgating a final rule which establishes procedures for conducting preliminary and formal safety investigations of events or practices at Department of Energy (DOE) defense nuclear facilities that the Board determines have adversely affected, or may adversely affect, public health and safety. The Board's experience in conducting formal safety investigations necessitates codifying the procedures set forth in this final rule. Among other benefits, these procedures will ensure a more efficient investigative process, protect confidential and privileged safety information, and promote uniformity of future safety investigations. The rule also promotes public awareness through greater transparency in the conduct of Board investigations.

DATES: This rule is effective December 1, 2014.

FOR FURTHER INFORMATION CONTACT: John G. Batherson, Associate General Counsel, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW., Suite 700, Washington, DC 20004, telephone (202) 694–7018, facsimile (202) 208–6518, email *JohnB@dnfsb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 27, 2012, the Board published a proposed rule in the **Federal Register** (77 FR 44174). The Board initially provided a 30-day public comment period for the proposed rule, and then extended the comment period an additional 30 days to September 26, 2012 (77 FR 51943). Subsequent to publication of the proposed rule and disposition of comments, but before the final rule was published, the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013 amended the Board's enabling legislation on January 2, 2013. The NDAA amendments required the Board to further modify the proposed rule. On August 11, 2014, the Board published a second notice of proposed rule in the **Federal Register** (79 FR 46720). The second notice of proposed rule incorporated changes necessitated by those NDAA amendments.

The Board is responsible for making recommendations to the Secretary of Energy and the President as the Board determines are necessary to ensure adequate protection of public health and safety at DOE defense nuclear facilities. The Board is vested with broad authority pursuant to 42 U.S.C. 2286a(b)(2) to investigate events or practices which have adversely affected, or may adversely affect, public health and safety at DOE's defense nuclear facilities. The Board is authorized to promulgate this final rule pursuant to its enabling legislation in the Atomic Energy Act of 1954, as amended, at 42 U.S.C. 2286b(c), which states that the Board may prescribe regulations to carry out its responsibilities. The final rule establishes a new Part 1708 in the Board's regulations, setting forth procedures governing the conduct of safety investigations.

It is imperative that Board investigators be able to obtain information from witnesses necessary to form an understanding of the underlying causes that adversely affect, or may adversely affect, public health and safety at DOE defense nuclear facilities. Frank communications are critical if Board investigators are to be effective. The Board must also be viewed as uncompromising in maintaining non-disclosure of privileged safety information. The Board must be able to assure complete confidentiality in order to encourage future witnesses to come forward.

The Board requires the discretion to offer individuals enforceable assurances of confidentiality in order to encourage their full and frank testimony. Without such authority, individuals may refrain from providing the Board with vital information affecting public health and safety, frustrating the efficient operation of the Board's oversight mission. To encourage candor and facilitate the free flow of information, the Board adopted in the proposed rule procedures to protect confidential statements from disclosure to the maximum extent permitted under existing law.

The Board received two formal comments on the July 27, 2012, (77 FR 44174) proposed rule: An email comment from Mr. Richard L. Urie, dated September 4, 2012, and a letter from Mr. Eric Fygi, DOE Deputy General

Counsel, dated September 26, 2012, submitted on behalf of DOE. The Board also became aware of additional commentary from Mr. Larry Brown, a former Board Member, published in the ''Weapons Complex Monitor.'' This commentary was not sent to the Board's contact point noticed in the proposed rule. However, the Board, in its discretion, decided to treat this commentary as having been submitted directly to the Board as a comment. The Board carefully considered each comment received, and made modifications to the proposed rule in response where appropriate. These modifications were published in the August 11, 2014, (79 FR 46720) second notice of proposed rule, along with a discussion of the disposition of comments received from the initial July 27, 2012, proposed rule and a request for additional comments. The Board received no additional comments on the second notice of proposed rule.

Regulatory Flexibility Act

For purposes of the Regulatory Flexibility Act, the rule will not have a significant economic impact on a substantial number of small entities. The rule addresses only the procedures to be followed in safety investigations. Accordingly, the Board has determined that a Regulatory Flexibility Analysis is not required.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995, the rule would not significantly or uniquely affect small governments and would not result in increased expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (as adjusted for inflation).

Executive Order 12866

In issuing this regulation, the Board has adhered to the regulatory philosophy and the applicable principles of regulation as set forth in section 1 of Executive Order 12866, Regulatory Planning and Review. This rule has not been reviewed by the Office of Management and Budget under that Executive Order since it is not a significant regulatory action within the meaning of the Executive Order.

Executive Order 12988

The Board has reviewed this regulation in light of section 3 of Executive Order 12988, Civil Justice Reform, and certifies that it meets the applicable standards provided therein.

Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this regulation does not contain information collection requirements that require approval by the Office of Management and Budget. The Board expects the collection of information that is called for by the regulation would involve fewer than 10 persons each year.

Congressional Review Act

The Board has determined that this rulemaking does not involve a rule within the meaning of the Congressional Review Act.

List of Subjects in 10 CFR Part 1708

Administrative practice, Procedure, and Safety investigations.

For the reasons stated in the preamble, the Defense Nuclear Facilities Safety Board adds a new Part 1708 to 10 CFR chapter XVII to read as follows:

PART 1708—PROCEDURES FOR SAFETY INVESTIGATIONS

Sec.

1708.100 Authority to conduct safety investigations.
1708.101 Scope and purpose of safety investigations.
1708.102 Types of safety investigations.
1708.103 Request to conduct safety investigations.
1708.104 Confidentiality of safety investigations and privileged safety information.
1708.105 Promise of confidentiality.
1708.106 Limitation on participation.
1708.107 Powers of persons conducting formal safety investigations.
1708.108 Cooperation: Ready access to facilities, personnel, and information.
1708.109 Rights of witnesses in safety investigations.
1708.110 Multiple interests.
1708.111 Sequestration of witnesses.
1708.112 Appearance and practice before the Board.
1708.113 Right to submit statements.
1708.114 Official transcripts.
1708.115 Final report of safety investigation.
1708.116 Procedure after safety investigations.

Authority: 42 U.S.C. 2286b(c); 42 U.S.C. 2286a(b)(2); 44 U.S.C. 3101–3107, 3301–3303a, 3308–3314.

§ 1708.100 Authority to conduct safety investigations.

(a) The Defense Nuclear Facilities Safety Board (Board) is an independent federal agency in the executive branch of the United States Government.

(b) The Board's enabling legislation authorizes it to conduct safety investigations pursuant to the Atomic Energy Act of 1954, as amended (42 U.S.C. 2286a(b)(2)).

§ 1708.101 Scope and purpose of safety investigations.

(a) The Board shall investigate any event or practice at a Department of Energy defense nuclear facility which the Board determines has adversely affected, or may adversely affect, public health and safety.

(b) The purpose of any Board investigation shall be:

(1) To determine whether the Secretary of Energy is adequately implementing standards (including all applicable Department of Energy orders, regulations, and requirements) at Department of Energy defense nuclear facilities;

(2) To ascertain information concerning the circumstances of such event or practice and its implications for such standards;

(3) To determine whether such event or practice is related to other events or practices at other Department of Energy defense nuclear facilities; and

(4) To provide to the Secretary of Energy such recommendations for changes in such standards or the implementation of such standards (including Department of Energy orders, regulations, and requirements) and such recommendations relating to data or research needs as may be prudent or necessary.

§ 1708.102 Types of safety investigations.

(a) The Board may initiate a preliminary safety inquiry or order a formal safety investigation.

(b) A preliminary safety inquiry means any inquiry conducted by the Board or its staff, other than a formal investigation. Where it appears from a preliminary safety inquiry that a formal safety investigation is appropriate, the Board's staff will so recommend to the Board.

(c) A formal safety investigation is instituted by an Order of Safety Investigation issued either after a recorded notational vote of Board Members or after convening a meeting in accordance with the Government in the Sunshine Act and voting in open or closed session, as the case may be.

(d) Orders of Safety Investigations will outline the basis for the investigation, the matters to be investigated, the Investigating Officer(s) designated to conduct the investigation, and their authority.

(e) The Office of the General Counsel shall have primary responsibility for conducting and leading a formal safety investigation. The Investigating Officer(s) shall report to the Board.

(f) Following a notational vote and in accordance with the Government in the Sunshine Act, the Board or an

individual Board Member authorized by the Board may hold such closed or open hearings and sit and act at such times and places, and require the attendance and testimony of such witnesses and the production of such evidence as the Board or an authorized member may find advisable, or exercise any other applicable authority as provided in the Board's enabling legislation. Each Board Member shall have full access to all information relating to the matter under investigation, including attendance at closed hearings.

(g) Subpoenas in formal safety investigation hearings may be issued by the Chairman only after a notational vote of the Board. The Chairman may designate another Board Member to issue a subpoena. Subpoenas shall be served by any person designated by the Chairman, or otherwise as provided by law.

(h) A determination of a decision or action authorized to the Board by these procedures shall only be made after a notational vote of the Board with each Board Member having one vote.

§ 1708.103 Request to conduct safety investigations.

(a) Any person may request that the Board perform a preliminary safety inquiry or conduct a formal safety investigation concerning a matter within the Board's jurisdiction.

(b) Actions the Board may take regarding safety investigation requests are discretionary.

(c) The Board will offer to protect the identity of a person requesting a safety investigation to the maximum extent permitted by law.

(d) Board safety investigations are wholly administrative and investigatory in nature and do not involve a determination of criminal culpability, adjudication of rights and duties, or other quasi-judicial determinations.

§ 1708.104 Confidentiality of safety investigations and privileged safety information.

(a) Information obtained during the course of a preliminary safety inquiry or a formal safety investigation may be treated as confidential, safety privileged, and non-public by the Board and its staff, to the extent permissible under existing law. The information subject to this protection includes but is not limited to: Identity of witnesses; recordings; statements; testimony; transcripts; emails; all documents, whether or not obtained pursuant to Board subpoena; any conclusions based on privileged safety information; any deliberations or recommendations as to policies to be pursued; and all other related investigative proceedings and activities.

(b) The Board shall have the discretion to assert the safety privilege when safety information, determined by the Board as protected from release, is sought by any private or public governmental entity or by parties to litigation who attempt to compel its release.

(c) Nothing in this section voids or otherwise displaces the Board's legal obligations with respect to the Freedom of Information Act, the Government in the Sunshine Act, or any procedures or requirements contained in the Board's regulations issued pursuant to those Acts.

§ 1708.105 Promise of confidentiality.

(a) The Investigating Officer(s) may give a promise of confidentiality to any individual who provides evidence for a safety inquiry or investigation to encourage frank communication.

(b) A promise of confidentiality must be explicit.

(c) A promise of confidentiality must be documented in writing.

(d) A promise of confidentiality may be given only as needed to ensure forthright cooperation of a witness and may not be given on a blanket basis to all witnesses.

(e) A promise of confidentiality must inform the witness that it applies only to information given to the Investigating Officer(s) and not to the same information if given to others.

§ 1708.106 Limitation on participation.

(a) A safety investigation under this rule is not a judicial or adjudicatory proceeding.

(b) No person or entity has standing to intervene or participate as a matter of right in any safety investigation under this regulation.

§ 1708.107 Powers of persons conducting formal safety investigations.

The Investigating Officer(s) appointed by the Board may take informal or formal statements, interview witnesses, take testimony, request production of documents, recommend issuance of subpoenas, recommend taking of testimony in a closed forum, recommend administration of oaths, and otherwise perform any lawful act authorized under the Board's enabling legislation in connection with any safety investigation ordered by the Board.

§ 1708.108 Cooperation: Ready access to facilities, personnel, and information.

(a) Section 2286c(a) of the Atomic Energy Act of 1954, as amended, requires the Department of Energy to fully cooperate with the Board and provide the Board with ready access to such facilities, personnel, and information as the Board considers necessary, including ready access in connection with a safety investigation.

(b) Each contractor operating a Department of Energy defense nuclear facility under a contract awarded by the Secretary is also required, to the extent provided in such contract or otherwise with the contractor's consent, to fully cooperate with the Board and provide the Board with ready access to such facilities, personnel, and information of the contractor as the Board considers necessary in connection with a safety investigation.

(c) The Board may make a written request to persons or entities relevant to the safety investigation to preserve pertinent information, documents, and evidence, including electronically stored information, in order to preclude alteration or destruction of that information.

§ 1708.109 Rights of witnesses in safety investigations.

(a) Any person who is compelled to appear in person to provide testimony or produce documents in connection with a safety investigation is entitled to be accompanied, represented, and advised by an attorney. Subpoenas in safety investigations shall issue only under signature of the Chairman or any Member of the Board designated by the Chairman. Attendance and testimony shall be before the Board or a Member authorized by the Board.

(b) If an executive branch agency employee witness is represented by counsel from that same agency, counsel shall identify who counsel represents to determine whether counsel represents multiple interests in the safety investigation.

(c) Counsel for a witness may advise the witness with respect to any question asked where it is claimed that the testimony sought from the witness is outside the scope of the safety investigation, or that the witness is privileged to refuse to answer a question or to produce other evidence. For these permissible objections, the witness or counsel may object on the record to the question and may state briefly and precisely the grounds therefore. If the witness refuses to answer a question, then counsel may briefly state on the record that counsel has advised the witness not to answer the question and the legal grounds for such refusal. The witness and his or her counsel shall not otherwise object to or refuse to answer any question, and they shall not otherwise interrupt any oral examination.

(d) When it is claimed that the witness has a privilege to refuse to answer a question on the grounds of self-incrimination, the witness must assert the privilege personally.

(e) Any objections made during the course of examination will be treated as continuing objections and preserved throughout the further course of testimony without the necessity for repeating them as to any similar line of inquiry.

(f) Counsel for a witness may not interrupt the examination by making any unnecessary objections or statements on the record.

(g) Following completion of the examination of a witness, such witness may make a statement on the record, and that person's counsel may, on the record, question the witness to enable the witness to clarify any of the witness's answers or to offer other evidence.

(h) The Board or any Member authorized by the Board shall take all measures necessary to regulate the course of an investigative proceeding to avoid delay and prevent or restrain obstructionist or contumacious conduct or contemptuous language.

(i) If the Board or any Member authorized by the Board finds that counsel for a witness, or other representative, has refused to comply with his or her directions, or has engaged in obstructionism or contumacy, the Board or Member authorized by the Board may thereupon take action as the circumstances may warrant.

(j) Witnesses appearing voluntarily do not have a right to have counsel present during questioning, although the Board or Member authorized by the Board, in consultation with the Office of the General Counsel, may permit a witness appearing on a voluntary basis to be accompanied by an attorney or non-attorney representative.

§ 1708.110 Multiple interests.

(a) If counsel representing a witness appears in connection with a safety investigation, counsel shall state on the record all other persons or entities counsel represents in that investigation.

(b) When counsel does represent more than one person or entity in a safety investigation, counsel shall inform the Investigating Officer(s) and each client of counsel's possible conflict of interest in representing that client.

(c) When an Investigating Officer(s), or the Board, as the case may be, in consultation with the Board's General Counsel, has concrete evidence that the presence of an attorney representing multiple interests would obstruct or impede the safety investigation, the Investigating Officer(s) or the Board may prohibit that attorney from being present during testimony.

(d) The Board shall issue a written statement of the reasons supporting a decision to exclude counsel under this section within five working days following exclusion. The Board shall also delay the safety investigation for a reasonable period of time to permit retention of new counsel.

§ 1708.111 Sequestration of witnesses.

(a) Witnesses shall be sequestered during interviews, or during the taking of testimony, unless otherwise permitted by the Investigating Officer(s) or by the Board, as the case may be.

(b) No witness, or counsel accompanying any such witness, shall be permitted to be present during the examination of any other witness called in such proceeding, unless permitted by the Investigating Officer(s) or the Board, as the case may be.

§ 1708.112 Appearance and practice before the Board.

(a) Counsel appearing before the Board or the Investigating Officer(s) must conform to the standards of ethical conduct required of practitioners before the Courts of the United States.

(b) The Board may suspend or deny, temporarily or permanently, the privilege of appearing or practicing before the Board in any way to a person who is found:

(1) Not to possess the requisite qualifications to represent others; or

(2) To have engaged in unethical or improper professional conduct; or

(3) To have engaged in obstructionism or contumacy before the Board; or

(4) To be otherwise not qualified.

(c) Obstructionist or contumacious conduct in an investigation before the Board or the Investigating Officer(s) will be grounds for exclusion of any person from such safety investigation proceedings and for summary suspension for the duration of the investigation.

(d) At the time of the finding the Board shall issue a verbal or written statement of the reasons supporting a decision to suspend or exclude counsel for obstructionism or contumacy.

(e) A witness may have a reasonable amount of time to retain replacement counsel if original counsel is suspended or excluded.

§ 1708.113 Right to submit statements.

At any time during the course of an investigation, any person may submit documents, statements of facts, or memoranda of law for the purpose of explanation or further development of the facts and circumstances relevant to the safety matter under investigation.

§ 1708.114 Official transcripts.

(a) Official transcripts of witness testimony, whether or not compelled by subpoena to appear before a Board safety investigation, shall be recorded either by an official reporter or by any other person or means designated by the Investigating Officer(s) or the Board's General Counsel.

(b) Such witness, after completing the compelled testimony, may file a request with the Board's General Counsel to procure a copy of the official transcript of that witness's testimony. The General Counsel shall rule on the request, and may deny for good cause.

(c) Good cause for denying a witness's request to procure a transcript may include, but shall not be limited to, the protection of a trade secret, non-disclosure of confidential or proprietary business information, security-sensitive operational or vulnerability information, safety privileged information, or the integrity of Board investigations.

(d) Whether or not a request is made, the witness and his or her attorney shall have the right to inspect the official transcript of the witness's own testimony, in the presence of the Investigating Officer(s) or his designee, for purposes of conducting errata review.

(e) Transcripts of testimony are otherwise considered confidential and privileged safety information, and in no case shall a copy or any reproduction of such transcript be released to any other person or entity, except as provided in paragraph (b) above or as required under the Freedom of Information Act or the Government in the Sunshine Act, or any procedures or requirements contained in Board regulations issued pursuant to those Acts.

§ 1708.115 Final report of safety investigation.

(a) The Board will complete a final report of the safety investigation fully setting forth the Board's findings and conclusions.

(b) The final report of the safety investigation is confidential and protected by the safety privilege, and is therefore not releasable.

(c) The Board, in its discretion, may sanitize the final report of the safety investigation by redacting confidential and safety privileged information so that the report is put in a publically releasable format.

(d) Nothing in this section voids or otherwise displaces the Board's legal obligations with respect to compliance

with the Freedom of Information Act, the Government in the Sunshine Act, or any procedures or requirements contained in the Board's regulations issued pursuant to those Acts.

§ 1708.116 Procedure after safety investigations.

(a) If a formal safety investigation results in a finding that an event or practice has adversely affected, or may adversely affect, public health and safety, the Board may take any appropriate action authorized to it under its enabling statute, including, but not limited to, making a formal recommendation to the Secretary of Energy, convening a hearing, or establishing a reporting requirement.

(b) If a safety investigation yields information relating to violations of federal criminal law involving government officers and employees, the Board shall expeditiously refer the matter to the Department of Justice for disposition.

(c) If in the course of a safety investigation, a safety issue or concern is found to be outside the Board's jurisdiction, that safety issue or concern shall be referred to the appropriate entity with jurisdiction for disposition.

(d) Statements made in connection with testimony provided to the Board in an investigation are subject to the provisions of 18 U.S.C. 1001.

Dated: November 24, 2014.

Peter S. Winokur,

Chairman.

[FR Doc. 2014–28248 Filed 11–28–14; 8:45 am]

BILLING CODE 3670–01–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 730, 734, 736, 742, 744, and 745

[Docket No. 141114962–4962–01]

RIN 0694–AG39

Updated Statements of Legal Authority for the Export Administration Regulations

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule updates the Code of Federal Regulations (CFR) legal authority paragraphs in the Export Administration Regulations (EAR) to cite the most recent Presidential notice extending an emergency declared pursuant to the International Emergency Economic Powers Act. This is a procedural rule that only updates authority paragraphs of the EAR. It does not alter any right, obligation or prohibition that applies to any person under the EAR.

DATES: The rule is effective December 1, 2014.

FOR FURTHER INFORMATION CONTACT: William Arvin, Regulatory Policy Division, Bureau of Industry and Security, Telephone: (202) 482–2440.

SUPPLEMENTARY INFORMATION:

Background

Authority for EAR parts 730, 734, 736, 742, 744 & 745 rests, in part, on Executive Order 12938 of November 14, 1994—National Emergency With Respect to Weapons of Mass Destruction, 59 FR 59099, 3 CFR, 1994 Comp., p. 950 and on annual notices extending the emergency declared in that executive order. This rule revises the authority paragraphs for the affected parts to cite the most recent such notice, which the President signed on November 7, 2014.

This rule is purely procedural, and makes no changes other than to revise CFR authority paragraphs for the purpose of making the authority citations current. It does not change the text of any section of the EAR, nor does it alter any right, obligation or prohibition that applies to any person under the EAR.

Rulemaking Requirements

1. 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, distributive impacts, and equity). This rule does not impose any regulatory burden on the public and is consistent with the goals of Executive Order 13563. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule does not involve any collection of information.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. The Department finds that there is good cause under 5 U.S.C. 553(b)(B) to waive the provisions of the Administrative Procedure Act requiring prior notice and the opportunity for public comment because they are unnecessary. This rule only updates legal authority citations. It clarifies information and is non-discretionary. This rule does not alter any right, obligation or prohibition that applies to any person under the EAR. Because these revisions are not substantive changes, it is unnecessary to provide notice and opportunity for public comment. In addition, the 30-day delay in effectiveness required by 5 U.S.C. 553(d) is not applicable because this rule is not a substantive rule. Because neither the Administrative Procedure Act nor any other law requires that notice of proposed rulemaking and an opportunity for public comment be given for this rule, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable.

List of Subjects

15 CFR Part 730

Administrative practice and procedure, Advisory committees, Exports, Reporting and recordkeeping requirements, Strategic and critical materials.

15 CFR Part 734

Administrative practice and procedure, Exports, Inventions and patents, Research, Science and technology.

15 CFR Part 736

Exports.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 745

Administrative practice and procedure, Chemicals, Exports, Foreign trade, Reporting and recordkeeping requirements.

Accordingly, parts 730, 734, 736, 742, 744 and 745 of the EAR (15 CFR parts 730–774) are amended as follows:

PART 730—[AMENDED]

■ 1. The authority citation for 15 CFR part 730 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 7420; 10 U.S.C.

7430(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note; 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 11912, 41 FR 15825, 3 CFR, 1976 Comp., p. 114; E.O. 12002, 42 FR 35623, 3 CFR, 1977 Comp., p. 133; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12214, 45 FR 29783, 3 CFR, 1980 Comp., p. 256; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 179; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 12981, 60 FR 62981, 3 CFR, 1995 Comp., p. 419; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p 168; E.O. 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013); Notice of January 21, 2014, 79 FR 3721 (January 22, 2014); Notice of May 7, 2014, 79 FR 26589 (May 9, 2014); Notice of August 7, 2014, 79 FR 46959 (August 11, 2014); Notice of September 17, 2014, 79 FR 56475 (September 19, 2014); Notice of November 7, 2014, 79 FR 67035 (November 12, 2014).

PART 734—[AMENDED]

■ 2. The authority citation for 15 CFR part 734 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013); Notice of August 7, 2014, 79 FR 46959 (August 11, 2014); Notice of November 7, 2014, 79 FR 67035 (November 12, 2014).

PART 736—[AMENDED]

■ 3. The authority citation for 15 CFR part 736 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 2151 note; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; Notice of May 7, 2014, 79 FR 26589 (May 9, 2014); Notice of August 7, 2014, 79 FR 46959 (August 11, 2014); Notice of November 7, 2014, 79 FR 67035 (November 12, 2014).

PART 742—[AMENDED]

■ 4. The authority citation for 15 CFR part 742 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014); Notice of November 7, 2014, 79 FR 67035 (November 12, 2014).

PART 744—[AMENDED]

■ 5. The authority citation for 15 CFR part 744 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of January 21, 2014, 79 FR 3721 (January 22, 2014); Notice of August 7, 2014, 79 FR 46959 (August 11, 2014); Notice of September 17, 2014, 79 FR 56475 (September 19, 2014); Notice of November 7, 2014, 79 FR 67035 (November 12, 2014).

PART 745—[AMENDED]

■ 11. The authority citation for 15 CFR part 745 is revised to read as follows:

Authority: 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of November 7, 2014, 79 FR 67035 (November 12, 2014).

Dated: November 24, 2014.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2014–28235 Filed 11–28–14; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 748

[Docket No. 141114969–4969–01]

RIN 0694–AG36

Amendments to Existing Validated End-User Authorization in the People's Republic of China: Lam Research Service Co., Ltd.

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to revise the existing authorization for Validated End User (VEU) Lam Research Service Co., Ltd. (Lam) in the People's Republic of China (PRC). Specifically, BIS amends Supplement No. 7 to part 748 of the EAR to change two addresses for Lam's eligible facilities (also known as ''eligible destinations''), remove two existing facilities, and add eight eligible facilities.

DATES: This rule is effective December 1, 2014.

FOR FURTHER INFORMATION CONTACT: Mi-Yong Kim, Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, U.S. Department of Commerce, Phone: 202/482–5991; Fax: 202/482–3911; Email: *ERC@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

Authorization Validated End-User

Validated End Users (VEUs) are designated entities located in eligible destinations to which eligible items may be exported, reexported, or transferred (in-country) under a general authorization instead of a license. The names of the VEUs, as well as the dates they were so designated, and their respective eligible destinations and items are identified in Supplement No. 7 to part 748 of the EAR. Under the terms described in that supplement, VEUs may obtain eligible items without an export license from BIS, in conformity with Section 748.15 of the EAR. Eligible items vary between VEUs and may include commodities, software, and technology, except those controlled for missile technology or crime control reasons on the Commerce Control List (CCL) (part 774 of the EAR).

VEUs are reviewed and approved by the U.S. Government in accordance with the provisions of Section 748.15 and Supplement Nos. 8 and 9 to part 748 of the EAR. The End-User Review Committee (ERC), composed of representatives from the Departments of State, Defense, Energy, and Commerce, and other agencies, as appropriate, is responsible for administering the VEU program. BIS amended the EAR in a final rule published on June 19, 2007 (72 FR 33646) to create Authorization VEU.

Amendments to Existing Validated End-User Authorization in the People's Republic of China (PRC)

Revisions to the List of ''Eligible Destinations'' for Validated End User Lam Research Service Co., Ltd. (Lam)

In this final rule, BIS amends Supplement No. 7 to part 748 of the EAR to revise Lam's VEU authorization. BIS is not making these changes in response to activities of concern. BIS is making these changes at the request of the company. Specifically, this rule changes the address of two Lam facilities in the PRC to which eligible items may be exported, reexported or transferred (in-country) using Authorization VEU. The two facilities (''Eligible destination'') and their respective current and new addresses are as follows:

Lam Research International Sarl (Lam Beijing Warehouse)

Current Address:

Lam Research International Sarl (Lam Beijing Warehouse), c/o Beijing Lam Electronics Tech Center, No. 8 Building No. 1, Disheng North Street, Beijing Economic & Technological Development Area, Beijing, China 100176.

New Address:

Lam Research International Sarl (Lam Beijing Warehouse), c/o Beijing Lam Electronics Tech Center, 1 Building, No. 28, Jinghai Second Road, BDA, Beijing, China 100176.

Lam Research Service Co., Ltd. (Beijing Branch)

Current Address:

Lam Research Service Co., Ltd. (Beijing Branch), Rm. 1010, Zhaolin Building, No. 15 Rong Hua Zhong Road, Beijing Economic & Technological Development Area, Beijing, China 100176.

New Address:

Lam Research Service Co., Ltd. Beijing Branch, 6th Floor, Building 52, No.2, Jingyuan North Street, Beijing Economic & Technological Development Area, Beijing, China 100176.

This rule does not change the eligible items, identified in Supplement No. 7 to part 748, that may be exported, reexported or transferred (in-country) to these two facilities.

This rule also removes two of Lam's existing eligible facilities. The facilities removed by this rule are as follows:

Lam Research Semiconductor (Suzhou) Co., Ltd. (Suzhou) A Division of Lam Research International Sarl, A–2 Building, Export Processing Zone, Suzhou New District, Jiangsu Province, China 215151.

Lam Research (Shanghai) Co., Ltd., No.1 Jilong Road, Room 424–2, Waigaoqiao Free Trade Zone, Shanghai, China 200131.

Finally, this rule adds eight facilities to Lam's authorization. As a result of this rule, Lam's total number of eligible facilities is 18. The eight new facilities and their respective eligible items (''Eligible items (by ECCN)'') are as follows:

New Facilities (1) through (6):

(1) Lam Research International Sarl (Lam Shanghai Warehouse Operator), c/o Shanghai Well-win Logistics Co., Ltd., No. 2667 Zuchongzhi Road, Pudong New District, Shanghai, China.

(2) Lam Research International Sarl (Lam Beijing Warehouse), c/o China International ElectronicService Company, 1 Building, No. 28, Jinghai Second Road, BDA, Beijing, China 100176.

(3) Lam Research International Sarl (Lam Beijing Warehouse), c/o Beijing STE International Logistics Co., Ltd., Building 3, No. 9 Ke Chuang Er Street, Beijing Economic & Technological Development Area, Beijing, China 100176.

(4) Lam Research International Sarl (Lam Dalian Warehouse), c/o JD Logistics Dalian Bonded Logistic Co., Ltd., No.1 Public Warehouse, Dalian Bonded Logistics Zone, Dalian, China 116600.

(5) Lam Research International Sarl (Lam Xi'an Warehouse), c/o VR International Logistics (Xi'an) Co., Ltd., No. 28 Information Road, EPZ B Zone, Xian New District, Xian, China 710119.

(6) Lam Research International Sarl (Wuxi Bonded Warehouse for CIQ inspection), c/o SinoTrans Jiangsu Fuchang Logistics Co., Ltd., No. 1 Xiqin Road, Area A, Export Processing Zone, New District, Wuxi, China 214028.

The eligible items for new facilities (1) through (6) are 2B230, 2B350.c, 2B350.d, 2B350.g, 2B350.h, 2B350.i, 3B001.c and 3B001.e (items classified under ECCNs 3B001.c and 3B001.e are limited to ''specially designed'' components and accessories), 3D001 (limited to ''software'' (excluding source code) ''specially designed'' for the ''development'' or ''production'' of equipment controlled by ECCN 3B001), 3D002 (limited to ''software'' (excluding source code) ''specially designed'' for the ''use'' of equipment controlled by ECCN 3B001), and 3E001 (limited to ''technology'' according to the General Technology Note for the ''development'' of equipment controlled by ECCN 3B001). These ECCNs are identified by a single asterisk in the ''Eligible items (by ECCN)'' Column of the entry for Lam in Supplement No. 7 to part 748.

New Facilities (7) and (8):

(7) Lam Research Service Co., Ltd. (Lam Dalian Representative Office), c/o Intel Semiconductor (Dalian) Ltd., No. 109 Huaihe Road East, Dalian Economic & Technical Development Area, Dalian, China 116600.

(8) Lam Research Service (Shanghai) Co., Ltd. Xi'an Branch, Room 602, Building G, Wangzuo Xiandai City, 35 Tangyan Road, Gaoxin District, Xi'an, China 710065.

The eligible items for new facilities (7) and (8) are as follows 2B230, 2B350.c, 2B350.d, 2B350.g, 2B350.h, 2B350.i, 3B001.c and 3B001.e (items classified under ECCNs 3B001.c and 3B001.e are limited to ''specially designed'' components and accessories), 3D001 (limited to ''software'' (excluding source code) ''specially designed'' for the ''development'' or ''production'' of equipment controlled by ECCN 3B001), 3D002 (limited to ''software'' (excluding source code) ''specially designed'' for the ''use'' of equipment controlled by ECCN 3B001), and 3E001 (limited to ''technology'' according to the General Technology Note for the ''development'' or ''production'' (limited to those stages that support integration, assembly (mounting), inspection, testing, and quality assurance) of equipment controlled by ECCN 3B001). These items are identified by two asterisks in the ''Eligible items (by ECCN)'' Column of the entry for Lam in Supplement No. 7 to part 748.

To conform with Section 772.1 of the EAR, this rule adds quotation marks to the term ''specially designed'' in the list of eligible items for Lam's facilities.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p.783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 7, 2014, 79 FR 46959 (August 11, 2014), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act.

BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. 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, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. This rule involves collections previously approved by the Office of Management and Budget (OMB) under Control Number 0694–0088, ''Multi-Purpose Application,'' which carries a burden hour estimate of 43.8 minutes to prepare and submit form BIS–748; and for recordkeeping, reporting and review requirements in connection with Authorization VEU, which carries an estimated burden of 30 minutes per submission. This rule is expected to result in a decrease in license applications submitted to BIS. Total burden hours associated with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) and OMB Control Number 0694–0088 are not expected to increase significantly as a result of this rule.

Notwithstanding any other provisions of law, no person is required to respond to, nor be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. Pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), BIS finds good cause to waive requirements that this rule be subject to notice and the opportunity for public comment because they are unnecessary. In determining whether to grant VEU designations, a committee of U.S. Government agencies evaluates information about and commitments made by candidate companies, the nature and terms of which are set forth in 15 CFR part 748, Supplement No. 8. The criteria for evaluation by the committee are set forth in 15 CFR 748.15(a)(2).

The information, commitments, and criteria for this extensive review were all established through the notice of proposed rulemaking and public comment process (71 FR 38313 (July 6, 2006) (proposed rule), and 72 FR 33646 (June 19, 2007) (final rule)). Given the similarities between the authorizations provided under the VEU program and export licenses (as discussed further below), the publication of this information does not establish new policy. In publishing this final rule, BIS updates addresses, adds eligible destinations, and removes eligible destinations of that VEU. These changes have been made within the established regulatory framework of the VEU program. Further, this rule does not abridge the rights of the public or eliminate the public's option to export under any of the forms of authorization set forth in the EAR.

Publication of this rule in other than final form is unnecessary because the authorizations granted in the rule are consistent with the authorizations granted to exporters for individual licenses (and amendments or revisions thereof), which do not undergo public review. In addition, as with license applications, VEU authorization applications contain confidential business information, which is necessary for the extensive review conducted by the U.S. Government in assessing such applications. This information is extensively reviewed according to the criteria for VEU authorizations, as set out in 15 CFR 748.15(a)(2). Additionally, just as the interagency reviews license applications, the authorizations granted under the VEU program involve interagency deliberation and result from review of public and non-public sources, including licensing data, and the measurement of such information against the VEU authorization criteria. Given the nature of the review, and in light of the parallels between the VEU application review process and the review of license applications, public comment on this authorization and subsequent amendments prior to publication is unnecessary. Moreover, because, as noted above, the criteria and process for authorizing and administering VEUs were developed with public comments, allowing additional public comment on this amendment to individual VEU authorizations, which was determined according to those criteria, is unnecessary.

Section 553(d) of the APA generally provides that rules may not take effect earlier than thirty (30) days after they are published in the **Federal Register**. BIS finds good cause to waive the 30-day delay in effectiveness under 5 U.S.C. 553(d)(3) because the delay would be contrary to the public interest. BIS is simply amending the authorization of an existing VEU by updating two addresses, removing two existing facilities, and adding eight additional facilities, consistent with established objectives and parameters administered and enforced by the responsible designated departmental representatives to the End-User Review Committee. Delaying this action's effectiveness could cause confusion regarding which facilitates and items are authorized by the U.S. Government and in turn stifle the purpose of the VEU Program. Accordingly, it is contrary to the public interest to delay this rule's effectiveness.

No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required under the APA or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. As a result, no final regulatory flexibility analysis is required and none has been prepared.

List of Subjects in 15 CFR Part 748

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

Accordingly, part 748 of the EAR (15 CFR parts 730–774) is amended as follows:

PART 748—[AMENDED]

■ 1. The authority citation for 15 CFR part 748 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014).

■ 2. Amend Supplement No. 7 to part 748 by revising the entry for ''Lam Research Service Co., Ltd.'' in ''China (People's Republic of)'' to read as follows:

SUPPLEMENT NO. 7 TO PART 748—AUTHORIZATION VALIDATED END-USER (VEU): LIST OF VALIDATED END-USERS, RESPECTIVE ITEMS ELIGIBLE FOR EXPORT, REEXPORT AND TRANSFER, AND ELIGIBLE DESTINATIONS

Country	Validated end-user	Eligible items (by ECCN)	Eligible destination	**Federal Register** citation
Nothing in this Supplement shall be deemed to supersede other provisions in the EAR, including but not limited to § 748.15(c).				
*	*	* *	* *	*
	Lam Research Service Co., Ltd.	*These Items Authorized for those Lam's Destinations Identified by a single asterisk (*):* 2B230, 2B350.c, 2B350.d, 2B350.g, 2B350.h, 2B350.i, 3B001.c and 3B001.e (items classified under ECCNs 3B001.c and 3B001.e are limited to ''specially designed'' components and accessories), 3D001 (limited to ''software'' (excluding source code) ''specially designed'' for the ''development'' or ''production'' of equipment controlled by ECCN 3B001), 3D002 (limited to ''software'' (excluding source code) ''specially designed'' for the ''use'' of equipment controlled by ECCN 3B001), and 3E001 (limited to ''technology'' according to the General Technology Note for the ''development'' of equipment controlled by ECCN 3B001).	*Lam Research International Sarl (Lam Shanghai Warehouse), c/o HMG Supply Chain (Shanghai) Co., Ltd., No. 3869, Longdong Avenue, Pudong New District, Shanghai, China 201203. *Lam Research International Sarl (Lam Shanghai Warehouse; WGQ Bonded Warehouse), c/o HMG Supply Chain (Shanghai) Co., Ltd., No. 55, Fei la Road, Waigaoqiao Free Trade Zone, Pudong New Area, Shanghai, China 200131. *Lam Research International Sarl (Lam Beijing Warehouse), c/o Beijing Lam Electronics Tech Center, 1 Building, No. 28, Jinghai Second Road, BDA, Beijing, China 100176. *Lam Research International Sarl (Wuxi EPZ Bonded Warehouse), c/o HMG WHL Logistic (Wuxi) Co., Ltd., 1st Fl, Area 4, No. 1, Plot J3, No. 5 Gaolang East Road, Export Processing Zone, Wuxi, China 214028. *Lam Research International Sarl (Lam Beijing Warehouse), c/o HMG Hi-tech Logistics (Beijing) Co., Ltd., Building 3, No. 9 Ke Chuang Er Street, Beijing Economic Technological Development Area, Beijing, China 100176. *Lam Research International Sarl (Wuhan TSS), c/o HMG Wuhan Logistic Co., Ltd., 1st-2nd Floor, Area B, No. 5 Building, Hua Shi Yuan Er Road, East-lake Hi-Tech Development Zone, Wuhan, Hubei Province, China 430223. *Lam Research International Sarl (Lam Shanghai Warehouse Operator), c/o Shanghai Well-win Logistics Co., Ltd., No. 2667 Zuchongzhi Road, Pudong New District, Shanghai, China. *Lam Research International Sarl (Lam Beijing Warehouse), c/o China International Electronic Service Company, 1 Building, No. 28, Jinghai Second Road, BDA, Beijing, China 100176. *Lam Research International Sarl (Lam Beijing Warehouse), c/o Beijing STE International Logistics Co., Ltd., Building 3, No. 9 Ke Chuang Er Street, Beijing Economic & Technological Development Area, Beijing, China 100176.	75 FR 62462, 10/12/10. 77 FR 10953, 2/24/12. 78 FR 3319, 1/16/13. 78 FR 54752, 9/6/13. 79 FR [INSERT PAGE NUMBER], 12/1/14.

SUPPLEMENT NO. 7 TO PART 748—AUTHORIZATION VALIDATED END-USER (VEU): LIST OF VALIDATED END-USERS, RESPECTIVE ITEMS ELIGIBLE FOR EXPORT, REEXPORT AND TRANSFER, AND ELIGIBLE DESTINATIONS—Continued

Country	Validated end-user	Eligible items (by ECCN)	Eligible destination	**Federal Register** citation
			*Lam Research International Sarl (Lam Dalian Warehouse), c/o JD Logistics Dalian bonded logistic Co., Ltd., No. 1 Public Warehouse, Dalian Bonded Logistics Zone, Dalian, China 116600. *Lam Research International Sarl (Lam Xi'an Warehouse), c/o VR International Logistics (Xi'an) Co., Ltd., No. 28 Information Road, EPZ B Zone, Xian New District, Xian, China 710119. *Lam Research International Sarl (Wuxi Bonded Warehouse for CIQ inspection), c/o SinoTrans Jiangsu Fuchang Logistics Co., Ltd., No. 1 Xiqin Road, Area A, Export Processing Zone, New District, Wuxi, China 214028.	
		These Items Authorized for those Lam's Destinations Identified by two asterisks (**): 2B230, 2B350.c, 2B350.d, 2B350.g, 2B350.h, 2B350.i, 3B001.c and 3B001.e (items classified under ECCNs 3B001.c and 3B001.e are limited to ''specially designed'' components and accessories), 3D001 (limited to ''software'' (excluding source code) ''specially designed'' for the ''development'' or ''production'' of equipment controlled by ECCN 3B001), 3D002 (limited to ''software'' (excluding source code) ''specially designed'' for the ''use'' of equipment controlled by ECCN 3B001), and 3E001 (limited to ''technology'' according to the General Technology Note for the ''development'' or ''production'' (limited to those stages that support integration, assembly (mounting), inspection, testing, and quality assurance) of equipment controlled by ECCN 3B001).	**Lam Research Service Co., Ltd., 1st Floor, Area C, Hua Hong Science & Technology Park, 177 Bi Bo Road, Zhangjiang Hi-Tech Park, Pudong, Shanghai, China 201203. **Lam Research Service Co., Ltd. Beijing Branch, 6th Floor, Building 52, No. 2, Jingyuan North Street, Beijing Economic & Technological Development Area, Beijing, China 100176. **Lam Research Service Co., Ltd., Wuxi Representative Office, Room 302, Building 6, Singapore International Park, No. 89 Xing Chuang Si Road, Wuxi New District, Wuxi, Jiangsu, China 214028. **Lam Research Service Co., Ltd., Wuhan Representative Office, Room 302, Guanggu Software Park, Building E4, No. 1 Guanshan Road, Donghu Development Zone, Wuhan, Hubei Province, China 430074. **Lam Research Service Co., Ltd. (Lam Dalian Representative Office), c/o Intel Semiconductor (Dalian) Ltd., No. 109 Huaihe Road East, Dalian Economic & Technical Development Area, Dalian, China 116600. **Lam Research Service (Shanghai) Co., Ltd. Xi'an Branch, Room 602, Building G, Wangzuo Xiandai City, 35 Tangyan Road, Gaoxin District, Xi'an, China, 710065	
*	*	*	*	*

Dated: November 24, 2014.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2014–28221 Filed 11–28–14; 8:45 am]

BILLING CODE 3510–33–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Valuation of Benefits and Assets; Expected Retirement Age

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This rule amends the Pension Benefit Guaranty Corporation's regulation on Allocation of Assets in Single-Employer Plans by substituting a new table for determining expected retirement ages for participants in pension plans undergoing distress or involuntary termination with valuation dates falling in 2015. This table is needed in order to compute the value of early retirement benefits and, thus, the total value of benefits under a plan.

DATES: *Effective Date:* January 1, 2015.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion (*Klion.Catherine@pbgc.gov*), Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: The Pension Benefit Guaranty Corporation (PBGC) administers the pension plan termination insurance program under Title IV of the Employee Retirement Income Security Act of 1974 (ERISA). PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) sets forth (in subpart B) the methods for valuing plan benefits of terminating single-employer plans covered under Title IV. Guaranteed benefits and benefit liabilities under a plan that is undergoing a distress termination must be valued in accordance with subpart B of part 4044. In addition, when PBGC terminates an underfunded plan involuntarily pursuant to ERISA section 4042(a), it uses the subpart B valuation rules to determine the amount of the plan's underfunding.

Under § 4044.51(b) of the asset allocation regulation, early retirement benefits are valued based on the annuity starting date, if a retirement date has been selected, or the expected retirement age, if the annuity starting date is not known on the valuation date. Sections 4044.55 through 4044.57 set forth rules for determining the expected retirement ages for plan participants entitled to early retirement benefits. Appendix D of part 4044 contains tables to be used in determining the expected early retirement ages.

Table I in appendix D (Selection of Retirement Rate Category) is used to determine whether a participant has a low, medium, or high probability of retiring early. The determination is based on the year a participant would reach ''unreduced retirement age'' (*i.e.,* the earlier of the normal retirement age or the age at which an unreduced benefit is first payable) and the participant's monthly benefit at unreduced retirement age. The table applies only to plans with valuation dates in the current year and is updated annually by the PBGC to reflect changes in the cost of living, etc.

Tables II–A, II–B, and II–C (Expected Retirement Ages for Individuals in the Low, Medium, and High Categories respectively) are used to determine the expected retirement age after the probability of early retirement has been determined using Table I. These tables establish, by probability category, the expected retirement age based on both the earliest age a participant could retire under the plan and the unreduced retirement age. This expected retirement age is used to compute the value of the early retirement benefit and, thus, the total value of benefits under the plan.

This document amends appendix D to replace Table I–14 with Table I–15 in order to provide an updated correlation, appropriate for calendar year 2015, between the amount of a participant's benefit and the probability that the participant will elect early retirement. Table I–15 will be used to value benefits in plans with valuation dates during calendar year 2015.

PBGC has determined that notice of, and public comment on, this rule are impracticable and contrary to the public interest. Plan administrators need to be able to estimate accurately the value of plan benefits as early as possible before initiating the termination process. For that purpose, if a plan has a valuation date in 2015, the plan administrator needs the updated table being promulgated in this rule. Accordingly, the public interest is best served by issuing this table expeditiously, without an opportunity for notice and comment, to allow as much time as possible to estimate the value of plan benefits with the proper table for plans with valuation dates in early 2015.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this regulation, the Regulatory Flexibility Act of 1980 does not apply (5 U.S.C. 601(2)).

List of Subjects in 29 CFR Part 4044

Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR part 4044 is amended as follows:

PART 4044—ALLOCATION OF ASSETS IN SINGLE–EMPLOYER PLANS

■ 1. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

■ 2. Appendix D to part 4044 is amended by removing Table I–14 and adding in its place Table I–15 to read as follows:

Appendix D to Part 4044—Tables Used to Determine Expected Retirement Age

TABLE I–15—SELECTION OF RETIREMENT RATE CATEGORY

[For Plans with valuation dates after December 31, 2014, and before January 1, 2016]

If participant reaches URA in year—	Participant's retirement rate category is—			
	Low [1] if monthly benefit at URA is less than—	Medium [2] if monthly benefit at URA is—		High [3] if monthly benefit at URA is greater than—
		From—	To—	
2016	618	618	2,610	2,610

TABLE I–15—SELECTION OF RETIREMENT RATE CATEGORY—Continued

[For Plans with valuation dates after December 31, 2014, and before January 1, 2016]

If participant reaches URA in year—	Participant's retirement rate category is—			
	Low [1] if monthly benefit at URA is less than—	Medium [2] if monthly benefit at URA is—		High [3] if monthly benefit at URA is greater than—
		From—	To—	
2017	631	631	2,667	2,667
2018	646	646	2,728	2,728
2019	661	661	2,791	2,791
2020	676	676	2,855	2,855
2021	691	691	2,921	2,921
2022	707	707	2,988	2,988
2023	724	724	3,057	3,057
2024	740	740	3,127	3,127
2025 or later	757	757	3,199	3,199

[1] Table II–A.
[2] Table II–B.
[3] Table II–C.

* * * * *

Issued in Washington, DC, this 24th day of November, 2014.

Judith Starr,

General Counsel, Pension Benefit Guaranty Corporation.

[FR Doc. 2014–28216 Filed 11–28–14; 8:45 am]

BILLING CODE 7709–02–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2014–0878]

RIN 1625–AA00

Safety Zone; Upper Mississippi River Between Mile 44 and 46; Thebes, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary Final Rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all waters of the Upper Mississippi River, extending the entire width from mile 44 and 46. This safety zone is needed to protect persons, property, and infrastructure from potential damage and safety hazards associated with the removal of two 16 inch Enterprise pipelines in the navigation channel. Entry into this zone is prohibited unless specifically authorized by the Captain of the Port (COTP) Ohio Valley or a designated representative.

DATES: This rule is effective without actual notice from December 1, 2014 until January 31, 2015. For the purposes of enforcement, actual notice will be used from November 1, 2014, until December 1, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2014–0878]. 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 MSU Paducah, U.S. Coast Guard; telephone 270–442–1621, email *Heather.Norman@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl F. Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

APA Administrative Procedures Act
BNM Broadcast Notice to Mariners
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
LNM Local Notice to Mariners
MM Mile Marker
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

The Coast Guard is issuing this temporary 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)(3)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule as it would be impracticable and contrary to the public interest. On 23 September 2014, the Coast Guard received information about the scope and extent of a project, beginning 02 October 2014, involving the removal of two 16 inch Enterprise pipelines located at MM 45, Upper Mississippi River, Thebes, IL. Removal operations are anticipated to be approximately 4 hours per day until completion. The Coast Guard determined that immediate action is necessary to establish a safety zone to protect life and property from the hazards associated with and resulting from the pipeline removal. The Coast Guard was not advised of the scope and extent of this potentially hazardous condition in sufficient time to publish a NPRM.

This safety zone may include closures and/or navigation restrictions and requirements that are vital to maintaining safe navigation on the Upper Mississippi River during the Enterprise pipeline removal. Therefore, delaying the effective date for this emergency safety zone to complete the NPRM process would be contrary to the public interest as it would delay the safety measures vital to safe navigation. Broadcast Notices to Mariners (BNM) and information sharing with the waterway users will update mariners of the restrictions, requirements, and

enforcement times during this emergency situation.

For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this emergency rule effective less than 30 days after publication in the **Federal Register**. Providing 30 days notice would be contrary to public interest because immediate action is needed to protect life and property from the hazards associated with the Enterprise pipeline removal.

B. Basis and Purpose

The legal basis and authorities for this rule are found in 33 U.S.C. 1231, 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to establish and define safety zones.

The purpose of this safety zone is to protect life and property from the hazards associated with the removal of two 16 inch pipelines at mile 45 Upper Mississippi River. The removal of the pipelines poses a hazard to vessel traffic while they are being removed. For this reason, the Coast Guard is prohibiting entry from mile 44 to 46 Upper Mississippi River by all vessels during the enforcement period announced by BNM unless authorized by the COTP Ohio Valley or a designated representative.

C. Discussion of the Temporary Final Rule

The Coast Guard is establishing a temporary safety zone for all vessel traffic on the Upper Mississippi River from mile 44 to mile 46, extending the entire width of the river. Entry into and through this zone is prohibited to all vessels and persons unless specifically authorized by the COTP Sector Ohio Valley or designated representative. This rule is effective from November 1, 2014 to January 31, 2015 or until pipeline removal is completed, whichever occurs first. Enforcement times and specific restrictions will be announced via BNM. The company completing this project states during the effective time of this safety zone, they anticipate the need to close the river for approximately 4 hours on one single occasion. Any exceptions to these operational restrictions must be authorized by the COTP Ohio Valley or a designated representative. The COTP or a designated representative may be contacted by telephone at 502–779–5422.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on a number of 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 Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. This rule establishes a temporary safety zone for vessels on all waters of the Upper Mississippi River, extending the entire width from mile 44 to mile 46. Notifications of enforcement times will be communicated to the marine community via BNM and through Local Notice to Mariners (LNM). The impacts on routine navigation are expected to be minimal as the restrictions will be enforced only as necessary while the pipelines are being removed at mile 45 Upper Mississippi River. The company completing this project states during the effective time of this safety zone, they anticipate the need to close the river for approximately 4 hours on one single occasions. After this removal is complete, the safety zone will be canceled. Additionally, deviation from the safety zone restriction may be requested from the COTP Ohio Valley or designated representative and will be considered on a case-by-case basis.

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 affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit the Upper Mississippi River, from mile 44 to mile 46 from November 1, 2014 to January 31, 2015. This safety zone will not have a significant economic impact on a substantial number of small entities. Traffic in this area is limited to almost entirely recreational vessels and commercial towing vessels, and the restrictions will be enforced only as necessary while removal of the pipeline is being completed. Enforcement times and specific restrictions will be announced via BNM, LNM, or through other public notice. The company completing this project states during the effective time of this safety zone, they anticipate the need to close the river for approximately 4 hours on one single occasion. When this work is completed, the safety zone will be canceled. Deviation from the safety zone restriction may be requested from the COTP Ohio Valley or designated representative and will be considered on a case-by-case basis.

3. 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 this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

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

4. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

5. 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 determined that this rule does not have implications for federalism.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. Technical Standards

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

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, 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 this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule involves the creation of a safety zone. The safety zone is implemented to protect persons and property due to removal of two 16 inch pipelines at mile 45 Upper Mississippi River. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist and a categorical exclusion determination will be made available as indicated under the **ADDRESSES** section. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. A new temporary § 165.T08–0878 is added to read as follows:

§ 165.T08–0878 Safety Zone; Upper Mississippi River MM 44 to 46, Thebes, IL.

(a) *Location.* The following area is a safety zone: all waters of the Upper Mississippi River from mile 44 to 46, Thebes, IL., extending the entire width of the Upper Mississippi River.

(b) *Effective dates.* This rule is effective from November 1, 2014 to January 31, 2015 or until pipeline removal is completed, whichever occurs first. Enforcement times and specific restrictions will be announced via Broadcast Notice to Mariners (BNM).

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone during the enforcement period is prohibited unless authorized by the Captain of the Port (COTP) Ohio Valley or a designated representative.

(2) All persons and vessels shall comply with the instructions of the COTP and designated on-scene patrol personnel. On-scene patrol personnel include commissioned, warrant, and petty officers of the U.S. Coast Guard.

(3) Persons or vessels may request deviation from the safety zone restriction prescribed under paragraph (c)(1) of this section from the COTP Ohio Valley or a designated representative who may be a commissioned, warrant, or petty officer of the Coast Guard. The COTP Ohio Valley may be contacted by telephone at 1–800–253–7465 or on VHF–FM channel 16.

(d) *Informational Broadcasts.* The Captain of the Port Ohio Valley or a designated representative will inform the public through broadcast notices to mariners of the enforcement period for the safety zone as well as any changes in the dates and times of enforcement.

Dated: October 2, 2014.

R.V. Timme,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2014–28270 Filed 11–28–14; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2014–0698]

RIN 1625–AA87

Security Zone; USCGC Hamilton Commissioning Ceremony, Charleston Harbor, Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary Final Rule.

SUMMARY: The Coast Guard is establishing a temporary security zone in the navigable waters of the Charleston Harbor, Charleston, SC within Coast Guard Sector Charleston's Captain of the Port Zone. The security zone is necessary to prevent damage or injury to vessels and to safeguard Charleston Harbor during the USCGC HAMILTON commissioning ceremony. Persons and vessels will be prohibited from entering, transiting through, anchoring in, or remaining within the security zone unless authorized by the Captain of the Port Charleston or a designated representative.

DATES: This rule is effective on December 5 and 6, 2014 and will be enforced from 8:00 a.m. to 4:00 p.m. on December 6, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2014–0698. 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 Chief Warrant Officer Christopher Ruleman, Sector Charleston Waterways Management, U.S. Coast Guard; telephone (843) 740–3184, email *christopher.l.ruleman@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

A. Regulatory Information

The Coast Guard is issuing this temporary 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 Coast Guard did not have sufficient time to publish an NPRM and to receive public comments prior to the event. Any delay in the effective date of this rule would be impracticable and contrary to the public interest. The event will occur before a notice-and-comment rulemaking could be completed, thereby jeopardizing the safety and security of the commissioning ceremony.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, delaying the effective date of this rule would be impracticable and contrary to the public interest.

B. Basis and Purpose

The legal basis for the rule is the Coast Guard's authority to establish regulated security zones and other limited access areas: 33 U.S.C. 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Department of Homeland Security Delegation No. 0170.1.

The security zone is necessary to safeguard the Port of Charleston during the USCGC HAMILTON commissioning ceremony.

C. 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 and 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 Executive Order 12866 or under section 1 of Executive Order 13563. The office of Management and Budget has not reviewed it under those Orders. The economic impact of this rule is not significant for the following reasons: (1) the security zone will only be enforced for a total of eight hours; (2) although persons and vessels may not enter, transit through, anchor in, or remain within the security zone without authorization from the Captain of the Port Charleston or a designated representative, they may operate in the surrounding area during the enforcement period; and (3) the Coast Guard will provide advance notification of the security zone to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

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 would affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit in a portion of the Charleston Harbor in Charleston, South Carolina from 8:00 a.m. until 4:00 p.m. on December 6, 2014.

For the reasons discussed in the Regulatory Planning and Review section above, this rule will not have a significant economic impact on a substantial number of small entities.

3. 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 this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

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

4. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on 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 determined that this rule does not have implications for federalism.

6. 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.

7. 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 expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. Technical Standards

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

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined 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 a security zone on waters of the Charleston Harbor, South Carolina during the USCGC HAMILTON commissioning ceremony on Saturday, December 6, 2014. Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the security zone unless authorized by the Captain of the Port Charleston or a designated representative. This rule is categorically excluded from further review under paragraph (34)(g) of Figure 2–1 of the Commandant Instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a temporary § 165.T07–0698 to read as follows:

§ 165.T07–0698 Security Zone; USCGC HAMILTON commissioning ceremony, Charleston Harbor, Charleston, SC.

(a) *Regulated Area.* The rule establishes a security zone on certain waters of the Charleston Harbor, South Carolina. The security zone will create a regulated area that encompasses a portion of the waterway; all waters of the Charleston Harbor within 500 yards of the South Carolina Ports Authority Union Street Pier.

(b) *Definition.* The term ''designated representative'' means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Charleston in the enforcement of the regulated area.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Charleston or a designated representative.

(2) Persons and vessels desiring to enter, transit through, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at 843–740–7050, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, or remain within the regulated area is granted by the Captain of the Port Charleston or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative.

(3) The Coast Guard will provide notice of the regulated area by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Effective and enforcement period.* This rule is effective on December 5 through 6, 2014 and will be enforced from 8:00 a.m. until 4:00 p.m. on December 6, 2014.

Dated: November 4, 2014.

R. R. Rodriguez,

Captain, U.S. Coast Guard, Captain of the Port Charleston.

[FR Doc. 2014–28271 Filed 11–28–14; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2014–0550; FRL–9919–87–Region 7]

Approval and Promulgation of Implementation Plans; State of Iowa; 2014 Iowa State Implementation Plan

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the State Implementation Plan (SIP) for the State of Iowa. This final action will approve a revision to Iowa's SIP for the 2006 24-hour $PM_{2.5}$ National Ambient Air Quality Standards (NAAQS). The proposed action was published in the **Federal Register** on August 11, 2014. As stated in the proposal, the SIP revision submitted by the state satisfies the applicable requirements of the Clean Air Act (CAA) and will keep the Muscatine County, Iowa area in attainment of the 2006 24-hour $PM_{2.5}$ NAAQS.

DATES: This final rule is effective on December 31, 2014.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2014–0550. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219. The Regional Office's official hours of business are Monday through Friday, 8:00 to 4:30 excluding Federal holidays. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Amy Algoe-Eakin, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at (913) 551–7942, or by email at *algoe-eakin.amy@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' or ''our'' refer to EPA. This section provides additional information by addressing the following:

I. What is being addressed in this document?
II. Have the requirements for approval of a SIP revision been met?
III. EPA's Response to Comments
IV. What action is EPA taking?
V. Statutory and Executive Order Reviews

I. What is being addressed in this document?

EPA is granting final approval to the Iowa SIP submitted in response to a July 14, 2011, SIP Call related to the 2006 24-hour $PM_{2.5}$ NAAQS. 76 FR 41424. EPA proposed approval of this SIP revision on August 11, 2014. 79 FR 46742. A complete background of this rulemaking can be found in the docket for the proposal.

II. Have the requirements for approval of a SIP revision been met?

The state submission has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. In addition, as explained above and in more detail in the technical support document which is part of this document, the revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

III. EPA's Response to Comments

The public comment period on EPA's proposed rule opened August 11, 2014, the date of its publication in the **Federal Register**, and closed on September 10, 2014. During this period, EPA received three comment letters from the Iowa Chapter of the Sierra Club, Iowa Environmental Council, and Clean Air Muscatine, Inc.

Comment 1: Two commenters commented on the negative effects of $PM_{2.5}$ emissions the citizens of Muscatine. One commenter stated that excessive $PM_{2.5}$ emissions ''deprive health people of their ability to live their lives as actively as they might wish.'' One commenter stated that $PM_{2.5}$ causes and exacerbates respiratory illness. A commenter also stated that excessive $PM_{2.5}$ emissions impede a community's ability to enjoy economic progress.

Response 1: EPA agrees that $PM_{2.5}$ emissions can have negative health and economic effects on a community. EPA issued a SIP Call to Iowa to address the violations of the 2006 24-hour $PM_{2.5}$ NAAQS in the Muscatine County, area. 76 FR 41424. The July 30, 2014, Technical Support Document (TSD) for this proposed action [1] shows that the monitored values are currently below the 2006 24-hour $PM_{2.5}$ NAAQS. In this SIP being finalized today the State of Iowa has identified permanent and enforceable strategies to provide for continued attainment.

Comment 2: Two commenters commented on the emissions from Grain Processing Corporation (GPC). Both commenters note that GPC has a history of pollution and violating the CAA. Both commenters noted the enforcement action taken by the Iowa Attorney General's office regarding violations at GPC. Both commenters also expressed concerns about GPC complying with the terms of the SIP.

Response 2: The final action today incorporates Iowa's SIP into the Federally-approved SIP. As a result, EPA will have the authority to enforce any violations of the SIP pursuant to section 113 of the CAA. EPA intends to monitor compliance with the obligations set forth in Iowa's SIP for the Muscatine County area to ensure the area continues to attain the NAAQS. Further, the SIP contingency measures provide, that if, after the implementation of controls, the area violates the standard, the contingency measures will go into effect to reduce $PM_{2.5}$ emissions in the Muscatine County area. These protections ensure that emission sources will comply with the terms of the SIP.

Comment 3: Two commenters stated that the 2017 attainment date was later than what was proposed in the SIP Call. One commenter stated that the technology to ''clean the air'' has been around for years and the corrective measures proposed are to be completed by 2017.

Response 3: The July 30, 2014, TSD for the proposed action [2] shows that the monitored values for $PM_{2.5}$ in the Muscatine area are currently below the 2006 24-hour $PM_{2.5}$ NAAQS and the State of Iowa has identified permanent and enforceable strategies to provide for continued attainment. Further, the TSD discusses the complexity of the projects GPC is implementing. The number of pollutant-reducing projects as well as the necessity of a phased construction

[1] 79 FR 43742 (August 11, 2014); EPA–R07–OAR–2014–0550; FRL 9915–02–Region 7.

[2] *Id.*

approach illustrate that the 2017 attainment date is as expeditious as practicable.

Comment 4: One commenter notes that the SIP submission from Iowa was a year later than what was proposed in the SIP Call.

Response 4: EPA agrees that State of Iowa did not submit the SIP to EPA within the timeframe identified in the SIP Call. However, the Muscatine County area is currently attaining the $PM_{2.5}$ 2006 24-hour NAAQS and in the SIP being finalized today, the State of Iowa has demonstrated permanent and enforceable strategies are in place to provide for continued attainment.

Comment 5: One commenter noted that the contingency measure triggers in the proposed action were different than what was stated in the SIP Call.

Response 5: In the SIP call, EPA stated that it did not intend for CAA section 175A(d) to apply literally to the Muscatine area, but rather provided that Iowa follow section 175A(d) as a guide for developing and implementing contingency measures. 76 FR 41428. At the time of the SIP Call, EPA believed it was reasonable to expect the 98th percentile would be the appropriate trigger for implementing contingency measures. 76 FR at 41426. After reviewing Iowa's SIP revision and the associated contingency measures, EPA believes that the SIP revision meets the requirements of the SIP Call. Iowa has used section 175A(d) as guidance in developing the contingency measures, as required by the SIP Call. The contingency measure trigger proposed by Iowa is also reasonable. The first contingency measure trigger using the design value, to determine whether there is a violation, is consistent with the 2006 $PM_{2.5}$ NAAQS. The second contingency measure trigger using the 98th percentile value is consistent with EPA's SIP Call. Iowa will immediately implement the contingency measures as described below, upon reaching the first trigger. EPA has carefully reviewed the control strategy and the contingency measures proposed and agrees that the design value trigger for the contingency measures is reasonable, given the strength of the control strategy and the contingency measures proposed and the current design value data of 28 $\mu g/m^3$.

Comment 6: One commenter noted that it was difficult for the public to meaningfully participate in the SIP process if EPA does not follow what was stated in a final SIP Call.

Response 6: EPA provided opportunity for public comment in accordance with the CAA for the SIP Call and the proposed rule to approve Iowa's SIP. The SIP Call provided requirements for the state to address and also identified that the state establish a specific date in its SIP revision by which the Muscatine area will attain the standard. Further, the SIP Call provided that EPA will then establish a specific date for attainment when the Agency takes action on the state's plan. In today's action after proposing this action and taking comment, EPA is finalizing that plan in accordance with the SIP Call. The public, including the commenter had adequate opportunity and did provide comment on EPA's proposed action.

IV. What action is EPA taking?

EPA is taking final action to grant full approval of Iowa's SIP revision to address the 2006 24-hour $PM_{2.5}$ NAAQS.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 30, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: November 14, 2014.

Karl Brooks,

Regional Administrator, Region 7.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 52 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart Q—Iowa

■ 2. In § 52.820, the table in paragraph (d) is amended by adding entries (29) through (109) in numerical order to read as follows:

§ 52.820 Identification of plan.

* * * * *

(d) * * *

EPA-APPROVED IOWA SOURCE—SPECIFIC ORDERS/PERMITS

Name of source	Order/permit No.	State effective date	EPA approval date	Explanation
* *	* *	*	* *	*
(29) Grain Processing Corporation.	Administrative Consent Order NO. 2014–AQ–A1.	2/14/2014	12/1/2014 [*Insert Federal Register citation*].	The last sentence of Paragraph 5, Section III and Section VI are not approved by EPA as part of the SIP.
(30) Muscatine Power and Water	Permit NO. 74–A–175–S3	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(31) Muscatine Power and Water	Permit NO. 80–A–006–S3	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(32) Muscatine Power and Water	Permit NO. 80–A–007–S3	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(33) Muscatine Power and Water	Permit NO. 80–A–191–P2	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(34) Muscatine Power and Water	Permit NO. 80–A–193–S3	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(35) Muscatine Power and Water	Permit NO. 80–A–194–S3	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(36) Muscatine Power and Water	Permit NO. 80–A–197–S2	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(37) Muscatine Power and Water	Permit NO. 80–A–200–S1	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(38) Muscatine Power and Water	Permit NO. 80–A–201–S1	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(39) Muscatine Power and Water	Permit NO. 80–A–202–S2	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(40) Muscatine Power and Water	Permit NO. 93–A–283–S2	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(41) Muscatine Power and Water	Permit NO. 93–A–288–S3	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(42) Muscatine Power and Water	Permit NO. 93–A–289–S3	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(43) Muscatine Power and Water	Permit NO. 93–A–290–S3	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(44) Muscatine Power and Water	Permit NO. 93–A–373–P2	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(45) Muscatine Power and Water	Permit NO. 00–A–638–S3	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(46) Muscatine Power and Water	Permit NO. 00–A–639–S1	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(47) Muscatine Power and Water	Permit NO. 00–A–689–S1	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(48) Muscatine Power and Water	Permit NO. 00–A–684–S1	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(49) Muscatine Power and Water	Permit NO. 00–A–686–S1	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(50) Muscatine Power and Water	Permit NO. 00–A–687–S1	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(51) Muscatine Power and Water	Permit NO. 01–A–193–S2	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(52) Muscatine Power and Water	Permit NO. 01–A–218–S1	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(53) Muscatine Power and Water	Permit NO. 01–A–456–S1	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(54) Muscatine Power and Water	Permit NO. 01–A–617–S1	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	

EPA-APPROVED IOWA SOURCE—SPECIFIC ORDERS/PERMITS—Continued

Name of source	Order/permit No.	State effective date	EPA approval date	Explanation
(55) Muscatine Power and Water	Permit NO. 04–A–618–S1	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(56) Muscatine Power and Water	Permit NO. 04–A–619–S1	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(57) Muscatine Power and Water	Permit NO. 11–A–562–S1	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(58) Muscatine Power and Water	Permit NO. 13–A–139	7/23/2013	12/1/2014 [*Insert Federal Register citation*].	
(59) Muscatine Power and Water	Permit NO. 13–A–140	7/23/2013	12/1/2014 [*Insert Federal Register citation*].	
(60) Muscatine Power and Water	Permit NO. 13–A–141	7/23/2013	12/1/2014 [*Insert Federal Register citation*].	
(61) Muscatine Power and Water	Permit NO. 13–A–142	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(62) Muscatine Power and Water	Permit NO. 13–A–143	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(63) Muscatine Power and Water	Permit NO. 13–A–146	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(64) Muscatine Power and Water	Permit NO. 13–A–147	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(65) Muscatine Power and Water	Permit NO. 13–A–148	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(66) Muscatine Power and Water	Permit NO. 13–A–150	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(67) Muscatine Power and Water	Permit NO. 13–A–151	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(68) Muscatine Power and Water	Permit NO. 13–A–152	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(69) Muscatine Power and Water	Permit NO. 13–A–153	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(70) Muscatine Power and Water	Permit NO. 13–A–154	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(71) Muscatine Power and Water	Permit NO. 13–A–155	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(72) Muscatine Power and Water	Permit NO. 13–A–157	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(73) Muscatine Power and Water	Permit NO. 13–A–158	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(74) Muscatine Power and Water	Permit NO. 13–A–159	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(75) Muscatine Power and Water	Permit NO. 13–A–161	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(76) Muscatine Power and Water	Permit NO. 80–A–196–S3	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(77) Muscatine Power and Water	Permit NO. 93–A–286–S4	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(78) Muscatine Power and Water	Permit NO. 01–A–457–S4	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(79) Muscatine Power and Water	Permit NO. 06–A–650–S2	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(80) Muscatine Power and Water	Permit NO. 13–A–160	7/22/2013	12/1/2014 [*Insert Federal Register citation*].	
(81) Union Tank Car Company ...	Permit NO. 93–A–251–S5	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(82) Union Tank Car Company ...	Permit NO. 93–A–252–S5	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(83) Union Tank Car Company ...	Permit NO. 93–A–253–S5	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(84) Union Tank Car Company ...	Permit NO. 93–A–254–S3	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(85) Union Tank Car Company ...	Permit NO. 00–A–1086–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(86) Union Tank Car Company ...	Permit NO. 00–A–1087–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(87) Union Tank Car Company ...	Permit NO. 00–A–1088–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(88) Union Tank Car Company ...	Permit NO. 93–A–255–S7	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(89) Union Tank Car Company ...	Permit NO. 96–A–629–S3	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	

EPA-APPROVED IOWA SOURCE—SPECIFIC ORDERS/PERMITS—Continued

Name of source	Order/permit No.	State effective date	EPA approval date	Explanation
(90) Union Tank Car Company ...	Permit NO. 96–A–630–S5	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(91) Union Tank Car Company ...	Permit NO. 96–A–631–S3	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(92) Union Tank Car Company ...	Permit NO. 96–A–636–S3	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(93) Union Tank Car Company ...	Permit NO. 00–A–529–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(94) Union Tank Car Company ...	Permit NO. 00–A–530–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(95) Union Tank Car Company ...	Permit NO. 00–A–531–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(96) Union Tank Car Company ...	Permit NO. 00–A–532–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(97) Union Tank Car Company ...	Permit NO. 00–A–533–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(98) Union Tank Car Company ...	Permit NO. 93–A–256–S6	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(99) Union Tank Car Company ...	Permit NO. 96–A–632–S5	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(100) Union Tank Car Company	Permit NO. 96–A–633–S5	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(101) Union Tank Car Company	Permit NO. 96–A–634–S5	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(102) Union Tank Car Company	Permit NO. 96–A–635–S5	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(103) Union Tank Car Company	Permit NO. 00–A–1089–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(104) Union Tank Car Company	Permit NO. 00–A–1090–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(105) Union Tank Car Company	Permit NO. 00–A–1091–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(106) Union Tank Car Company	Permit NO. 10–A–043–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(107) Union Tank Car Company	Permit NO. 09–A–009–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(108) Union Tank Car Company	Permit NO. 09–A–010–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	
(109) Union Tank Car Company	Permit NO. 94–A–434–S2	4/08/2013	12/1/2014 [*Insert Federal Register citation*].	

* * * * *

[FR Doc. 2014–28147 Filed 11–28–14; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 130402317–3966–02]

RIN 0648–XD636

Atlantic Highly Migratory Species; Commercial Aggregated Large Coastal Sharks (LCS) and Hammerhead Sharks in the Atlantic Region

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is closing the fisheries for commercial aggregated LCS and hammerhead sharks in the Atlantic region. This action is necessary because the commercial landings of Atlantic aggregated LCS for the 2014 fishing season have reached 80 percent of the available commercial quota as of November 14, 2014, and the fisheries are quota-linked under current regulations.

DATES: The commercial fisheries for Atlantic aggregated LCS and Atlantic hammerhead are closed effective 11:30 p.m. local time November 30, 2014, until the end of the 2014 fishing season on December 31, 2014, or until and if NMFS announces via a notice in the **Federal Register** that additional quota is available and the season is reopened.

FOR FURTHER INFORMATION CONTACT: Alexis Jackson or Karyl Brewster-Geisz 301–427–8503; fax 301–713–1917.

SUPPLEMENTARY INFORMATION: The Atlantic shark fisheries are managed under the 2006 Consolidated Highly Migratory Species (HMS) Fishery Management Plan (FMP), its amendments, and its implementing regulations (50 CFR part 635) issued under authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*).

Under § 635.5(b)(1), dealers must electronically submit reports on sharks that are first received from a vessel on a weekly basis through a NMFS-approved electronic reporting system. Reports must be received by no later than midnight, local time, of the first Tuesday following the end of the reporting week unless the dealer is otherwise notified by NMFS. Under § 635.28(b)(3), the quotas of certain species and/or management groups are linked. The quotas for aggregated LCS and hammerhead sharks in the Atlantic

region are linked (§ 635.28(b)(3)(i)). Under § 635.28(b)(2), when NMFS calculates that the landings for any species and/or management group of a linked group have reached or are projected to reach 80 percent of the available quota, NMFS will file for publication with the Office of the Federal Register a notice of closure for all of the species and/or management groups in a linked group that will be effective no fewer than 5 days from date of filing. From the effective date and time of the closure until and if NMFS announces, via a notice in the **Federal Register**, that additional quota is available and the season is reopened, the fishery for all linked species and/or management groups is closed, even across fishing years.

On July 3, 2013 (78 FR 40318), NMFS announced the final rule for Amendment 5a to the 2006 Consolidated HMS FMP, which, among other things, established new quotas for aggregated LCS and hammerhead sharks in the Atlantic region and linked the Atlantic aggregated LCS and Atlantic hammerhead shark management groups. As a result of the quota linkage, when the quota for one management group is reached and is closed, the other management group closes at the same time. On November 26, 2013 (78 FR 70500), NMFS announced that the commercial Atlantic aggregated LCS quota for 2014 was 168.9 metric tons (mt) dressed weight (dw) (372,552 lb dw), and the Atlantic hammerhead shark quota was 27.1 mt dw (59,736 lb dw).

Dealer reports recently received through November 14, 2014, indicate that 135.0 mt dw, or 80 percent, of the available Atlantic aggregated LCS quota has been landed, and that 10.1 mt dw, or 37 percent, of the available Atlantic hammerhead shark quota has been landed. Based on these dealer reports, NMFS estimates that the 80-percent limit specified for a closure notice in the regulations has been reached as of November 14, 2014. Accordingly, NMFS is closing both the commercial aggregated LCS and hammerhead management groups in the Atlantic region as of 11:30 p.m. local time November 30, 3014. All other shark species or management groups that are currently open will remain open, including the blue shark, porbeagle shark, and pelagic sharks other than porbeagle or blue shark management groups.

At § 635.27(b)(1), the boundary between the Gulf of Mexico region and the Atlantic region is defined as a line beginning on the East Coast of Florida at the mainland at 25°20.4′ N. lat, proceeding due east. Any water and land to the south and west of that boundary is considered for the purposes of monitoring and setting quotas, to be within the Gulf of Mexico region.

During the closure, retention of aggregated LCS and hammerhead sharks in the Atlantic region is prohibited for persons fishing aboard vessels issued a commercial shark limited access permit (LAP) under § 635.4. However, persons aboard a commercially-permitted vessel that is also properly permitted to operate as a charter vessel or headboat for HMS and is engaged in a for-hire trip could fish under the recreational retention limits for sharks and ''no sale'' provisions (§ 635.22(a) and (c)). Similarly, persons aboard a commercially-permitted vessel that possesses a valid shark research permit under § 635.32 and has a NMFS-approved observer onboard may continue to harvest and sell aggregated LCS and hammerhead sharks in the Atlantic region pursuant to the terms and conditions of the shark research permit.

During this closure, a shark dealer issued a permit pursuant to § 635.4 may not purchase or receive aggregated LCS and/or hammerhead sharks in the Atlantic region from a vessel issued an Atlantic Shark LAP, except that a permitted shark dealer or processor may possess aggregated LCS and/or hammerhead sharks in the Atlantic region that were harvested, off-loaded, and sold, traded, or bartered prior to the effective date of the closure and were held in storage, consistent with § 635.28(b)(5). Additionally, a permitted shark dealer or processor may possess aggregated LCS and/or hammerhead sharks in the Atlantic region that were harvested by a vessel issued a valid shark research fishery permit per § 635.32 that had a NMFS-approved observer onboard during the trip the sharks were taken on, as long as the LCS research fishery quota remains open. Similarly, a shark dealer issued a permit pursuant to § 635.4 may, in accordance with relevant state regulations, purchase or receive aggregated LCS and/or hammerhead sharks in the Atlantic region if the sharks were harvested, off-loaded, and sold, traded, or bartered from a vessel that fishes only in state waters and that has not been issued an Atlantic Shark LAP, HMS Angling permit, or HMS Charter/Headboat permit pursuant to § 635.4.

Classification

Pursuant to 5 U.S.C. 553(b)(B), the Assistant Administrator for Fisheries, NOAA (AA), finds that providing prior notice and public comment for this action is impracticable and contrary to the public interest because the fishery is currently underway and any delay in this action would result in overharvest of the quota and be inconsistent with management requirements and objectives. Similarly, affording prior notice and opportunity for public comment on this action is contrary to the public interest because if the quota is exceeded, the stock may be negatively affected and fishermen ultimately could experience reductions in the available quota and a lack of fishing opportunities in future seasons. For these reasons, the AA also finds good cause to waive the 30-day delay in effective date pursuant to 5 U.S.C. 553(d)(3). This action is required under § 635.28(b)(2) and is exempt from review under Executive Order 12866.

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

Dated: November 25, 2014.

Emily H. Menashes,

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

[FR Doc. 2014–28224 Filed 11–25–14; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 79, No. 230
Monday, December 1, 2014

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 915

[Docket No. AMS–FV–14–0080; FV15–915–1 CR]

Avocados Grown in South Florida; Continuance Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Referendum order.

SUMMARY: This document directs that a referendum be conducted among eligible producers of avocados grown in South Florida to determine whether they favor continuance of the marketing order regulating the handling of avocados grown in the production area.

DATES: The referendum will be conducted from January 12 through January 27, 2015. To vote in this referendum, producers must have produced Florida avocados within the designated production area during the period April 1, 2013, through March 31, 2014.

ADDRESSES: Copies of the marketing order may be obtained from the referendum agents at 1124 First Street South, Winter Haven, FL 33880, or the Office of the Docket Clerk, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Doris Jamieson, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA, 1124 First Street South, Winter Haven, FL 33880; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: *Doris.Jamieson@ams.usda.gov* or *Christian.Nissen@ams.usda.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to Marketing Order No. 915, as amended (7 CFR part 915), hereinafter referred to as the ''order,'' and the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act,'' it is hereby directed that a referendum be conducted to ascertain whether continuance of the order is favored by producers. The referendum shall be conducted from January 12 through January 27, 2015, among Florida avocados growers in the production area. Only Florida avocado producers that were engaged in the production of Florida avocado, during the period of April 1, 2013, through March 31, 2014, may participate in the continuance referendum.

USDA has determined that continuance referenda are an effective means for determining whether producers favor the continuation of marketing order programs. USDA would consider termination of the order if less than two-thirds of the producers voting in the referendum and less than two-thirds of the volume of Florida avocados represented in the referendum favor continuance. In evaluating the merits of continuance versus termination, USDA will not exclusively consider the results of the continuance referendum. USDA will also consider all other relevant information concerning the operation of the order and the relative benefits and disadvantages to producers, handlers, and consumers in order to determine whether continued operation of the order would tend to effectuate the declared policy of the Act.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the ballot materials to be used in the referendum have been submitted to and approved by the Office of Management and Budget (OMB) and have been assigned OMB No. 0581–0189, Generic Fruit Crops. It has been estimated that it will take an average of 20 minutes for each of the approximately 300 producers of Florida avocados to cast a ballot. Participation is voluntary. Ballots postmarked after January 27, 2015, will not be included in the vote tabulation.

Doris Jamieson and Christian D. Nissen of the Southeast Marketing Field Office, Fruit and Vegetable Program, AMS, USDA, are hereby designated as the referendum agents of the Secretary of Agriculture to conduct this referendum. The procedure applicable to the referendum shall be the ''Procedure for the Conduct of Referenda in Connection With Marketing Orders for Fruits, Vegetables, and Nuts Pursuant to the Agricultural Marketing Agreement Act of 1937, as Amended'' (7 CFR 900.400–900.407).

Ballots will be mailed to all producers of record and may also be obtained from the referendum agents, or from their appointees.

List of Subjects in 7 CFR Part 915

Avocados, Reporting and recordkeeping requirements.

Authority: 7 U.S.C. 601–674.

Dated: November 25, 2014.

Rex A. Barnes,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2014–28288 Filed 11–28–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0766; Directorate Identifier 2013–NE–26–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Canada Corp. Turboprop Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to revise airworthiness directive (AD) 2014–17–08 that applies to all Pratt & Whitney Canada Corp. (P&WC) PT6A–114 and PT6A–114A turboprop engines. AD 2014–17–08 requires initial and repetitive borescope inspections (BSIs) of compressor turbine (CT) blades, and the removal from service of blades that fail inspection. Since we issued AD 2014–17–08, P&WC developed an additional single crystal CT blade that corrects the unsafe condition. This proposed AD would retain all the requirements of AD 2014–17–08, add an additional single crystal CT blade that corrects the unsafe condition, reduce the affected population, and correct the Credit for Previous Action paragraph.

We are proposing this AD to prevent failure of CT blades, which could result in damage to the engine and damage to the airplane.

DATES: We must receive comments on this proposed AD by January 30, 2015.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

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

For service information identified in this proposed AD, contact Pratt & Whitney Canada Corp., 1000 Marie-Victorin, Longueuil, Quebec, Canada, J4G 1A1; phone: 800–268–8000; fax: 450–647–2888; Internet: *www.pwc.ca.* You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2013–0766; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the mandatory continuing airworthiness information, regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Robert Morlath, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7154; fax: 781–238–7199; email: *robert.c.morlath@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this NPRM. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0766; Directorate Identifier 2013–NE–26–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

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

Discussion

On August 18, 2014, we issued AD 2014–17–08, Amendment 39–17961 (79 FR 52172, September 3, 2014), (''AD 2014–17–08''), for all P&WC PT6A–114 and PT6A–114A turboprop engines. AD 2014–17–08 requires initial and repetitive BSIs of CT blades, and the removal from service of blades that fail inspection. AD 2014–17–08 resulted from several incidents of CT blade failure, causing power loss, and engine failure. We issued AD 2014–17–08 to prevent failure of CT blades, which could result in damage to the engine and damage to the airplane.

Actions Since AD 2014–17–08 Was Issued

Since we issued AD 2014–17–08 (79 FR 52172, September 3, 2014), P&WC developed a new single crystal CT blade, P/N 3079351–01, to correct the unsafe condition. The addition of this new P/N reduces the affected population. Finally, we determined that in AD 2014–07–08, we gave credit for action that is inapplicable to the unsafe condition. Specifically, in the Credit for Previous Action paragraph, the AD allows credit for a previously performed metallurgical examination of ''single crystal CT blades''. Metallurgical examination of single crystal CT blades is inapplicable to the non-single crystal CT blades referenced in Compliance paragraph (e)(1)(iii)(B) of this NPRM.

Relevant Service Information

We reviewed P&WC Service Bulletin (SB) No. PT6A–72–1669, Revision 9, dated June 28, 2013. The service information describes procedures for correcting the unsafe condition.

FAA's Determination

We are proposing this NPRM because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This NPRM would require initial and repetitive BSIs of CT blades, and the removal from service of blades that fail inspection. This NPRM would also require as a mandatory terminating action, replacement of non-single crystal CT blades with single crystal CT blades at the next shop visit. This NPRM also corrects the reference to single crystal CT blades in the Credit for Previous Action paragraph. This NPRM also reduces the affected population by introducing a new single crystal CT blade P/N that addresses the unsafe condition.

Costs of Compliance

We estimate that this proposed AD affects 300 engines installed on airplanes of U.S. registry. We also estimate that it would take about 4 hours per engine to perform the required inspection and 8 hours to replace the blades. The average labor rate is $85 per hour. Required parts cost about $59,334 per engine. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $18,106,200.

Authority for This Rulemaking

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

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

Regulatory Findings

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

responsibilities among the various levels of government.

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

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

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

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. Amend § 39.13 by removing airworthiness directive (AD) 2014–17–08, Amendment 39–17961 (79 FR 52172, September 3, 2014), and adding the following new AD:

Pratt & Whitney Canada Corp.: Docket No. FAA–2013–0766; Directorate Identifier 2013–NE–26–AD.

(a) Comments Due Date

We must receive comments by January 30, 2015.

(b) Affected ADs

This AD replaces AD 2014–17–08, Amendment 39–17961 (79 FR 52172, September 3, 2014).

(c) Applicability

This AD applies to all Pratt & Whitney Canada Corp. (P&WC) PT6A–114 and PT6A–114A turboprop engines.

(d) Unsafe Condition

This AD was prompted by several incidents of compressor turbine (CT) blade failure, causing power loss, and engine failure. We are issuing this AD to prevent failure of CT blades, which could lead to damage to the engine and damage to the airplane.

(e) Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) For engines installed with CT blades other than P&WC single crystal CT blades, part numbers (P/Ns) 3072791–01, 3072791–02, or 3079351–01, do the following:

(i) Until removed, per the requirements of this AD, borescope inspect the CT blade leading and trailing edges, within the following intervals, whichever occurs later:

(A) 150 operating hours after October 8, 2014; or

(B) 500 operating hours since new; or

(C) 500 operating hours since last borescope inspection (BSI) of the CT blades; or

(D) Before next flight after the effective date of this AD.

(ii) Thereafter, repeat the inspection required by paragraph (e)(1)(i) of this AD every 500 flight hours time since last inspection.

(iii) At the next hot section inspection (HSI) after the effective date of this AD, and each HSI thereafter, replace the complete set of CT blades with any of the following:

(A) New CT blades;

(B) CT blades that have passed a two-blade metallurgical inspection. Use paragraph 3.B., Accomplishment Instructions, of P&WC Service Bulletin (SB) No. PT6A–72–1669, Revision 9, dated June 28, 2013, to do the inspection; or

(C) P&WC single crystal CT blades, P/Ns 3072791–01, 3072791–02, or 3079351–01.

(2) Replacement of the complete set of CT blades with single crystal CT blades, P/Ns 3072791–01, 3072791–02, or 3079351–01 is terminating action for the requirements of paragraph (e)(1) of this AD.

(3) By October 8, 2017, replace the complete set of CT blades with P&WC single crystal CT blades, P/Ns 3072791–01, 3072791–02, or 3079351–01.

(g) Credit for Previous Action

Performance of the metallurgical examination specified in paragraph (e)(1)(iii)(B) of this AD on CT blades other than P&WC single crystal CT blades, P/Ns 3072791–01, 3072791–02, or 3079351–01, before the effective date of this AD fulfils the initial inspection requirements of paragraph (e)(1)(i) of this AD. However, you must still comply with the repetitive BSI requirement of paragraph (e)(1)(ii) of this AD until you complete the mandatory terminating action of paragraph (e)(3) of this AD.

(h) Alternative Methods of Compliance (AMOCs)

(1) AMOCs previously approved for AD 2014–17–08, Amendment 39–17961 (79 FR 52172, September 3, 2014) are approved for this AD.

(2) The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE–AD–AMOC@faa.gov.*

(i) Related Information

(1) For more information about this AD, contact Robert Morlath, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7154; fax: 781–238–7199; email: *robert.c.morlath@faa.gov.*

(2) Refer to MCAI Transport Canada Civil Aviation AD CF–2013–21R1, dated November 13, 2013, for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2013-0766-0008.*

(3) P&WC SB No. PT6A–72–1669, Revision 9, dated June 28, 2013, which is not incorporated by reference in this AD, can be obtained from P&WC, using the contact information in paragraph (i)(4) of this AD.

(4) For service information identified in this AD, contact Pratt & Whitney Canada Corp., 1000 Marie-Victorin, Longueuil, Quebec, Canada, J4G 1A1; phone: 800–268–8000; fax: 450–647–2888; Internet: *www.pwc.ca.*

(5) Guidance for performing the BSI of the CT blades leading and trailing edges can be found in paragraph 3.A, Accomplishment Instructions, P&WC SB No. PT6A–72–1669, Revision 9, dated June 28, 2013.

(6) You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on November 20, 2014.

Colleen M. D'Alessandro,

Assistant Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2014–28188 Filed 11–28–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0779; Directorate Identifier 2014–NM–052–AD]

RIN 2120–AA64

Airworthiness Directives; Lockheed Martin Corporation/Lockheed Martin Aeronautics Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Lockheed Martin Corporation/Lockheed Martin Aeronautics Company Model 382, 382B, 382E, 382F, and 382G airplanes. This proposed AD was prompted by an evaluation by the design approval holder (DAH) indicating that the outer wings are subject to widespread fatigue damage (WFD). This proposed AD would

require replacing certain outer wings with new or certain serviceable outer wings. We are proposing this AD to prevent fatigue cracking of the outer wing, and to prohibit exceeding the limit of validity (LOV), which could result in reduced structural integrity of the airplane.

DATES: We must receive comments on this proposed AD by January 15, 2015.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

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

For service information identified in this proposed AD, contact Lockheed Martin Corporation/Lockheed Martin Aeronautics Company, Airworthiness Office, Dept. 6A0M, Zone 0252, Column P–58, 86 S. Cobb Drive, Marietta, GA 30063; telephone 770–494–5444; fax 770–494–5445; email *ams.portal@lmco.com;* Internet *http://www.lockheedmartin.com/ams/tools/TechPubs.html.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0779; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Carl Gray, Aerospace Engineer, Airframe Branch, ACE–117A, FAA, Atlanta Aircraft Certification Office (ACO), 1701 Columbia Avenue, College Park, GA 30337; phone: 404–474–5554; fax: 404–474–5605; email: *Carl.W.Gray@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2014–0779; Directorate Identifier 2014–NM–052–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

Structural fatigue damage is progressive. It begins as minute cracks, and those cracks grow under the action of repeated stresses. This can happen because of normal operational conditions and design attributes, or because of isolated situations or incidents such as material defects, poor fabrication quality, or corrosion pits, dings, or scratches. Fatigue damage can occur locally, in small areas or structural design details, or globally. Global fatigue damage is general degradation of large areas of structure with similar structural details and stress levels. Multiple-site damage is global damage that occurs in a large structural element such as a single rivet line of a lap splice joining two large skin panels. Global damage can also occur in multiple elements such as adjacent frames or stringers. Multiple-site-damage and multiple-element-damage cracks are typically too small initially to be reliably detected with normal inspection methods. Without intervention, these cracks will grow, and eventually compromise the structural integrity of the airplane, in a condition known as WFD. As an airplane ages, WFD will likely occur, and will certainly occur if the airplane is operated long enough without any intervention.

The FAA's WFD final rule (75 FR 69746, November 15, 2010) became effective on January 14, 2011. The WFD rule requires certain actions to prevent structural failure due to WFD throughout the operational life of certain existing transport category airplanes and all of these airplanes that will be certificated in the future. For existing and future airplanes subject to the WFD rule, the rule requires that DAHs establish a limit of validity (LOV) of the engineering data that support the structural maintenance program. Operators affected by the WFD rule may not fly an airplane beyond its LOV, unless an extended LOV is approved.

The WFD rule (75 FR 69746, November 15, 2010) does not require identifying and developing maintenance actions if the DAHs can show that such actions are not necessary to prevent WFD before the airplane reaches the LOV. Many LOVs, however, do depend on accomplishment of future maintenance actions. As stated in the WFD rule, any maintenance actions necessary to reach the LOV will be mandated by airworthiness directives through separate rulemaking actions.

In the context of WFD, this action is necessary to enable DAHs to propose LOVs that allow operators the longest operational lives for their airplanes, and still ensure that WFD will not occur. This approach allows for an implementation strategy that provides flexibility to DAHs in determining the timing of service information development (with FAA approval), while providing operators with certainty regarding the LOV applicable to their airplanes.

This proposed AD for all Lockheed Martin Corporation/Lockheed Martin Aeronautics Company Model 382, 382B, 382E, 382F, and 382G airplanes was prompted by an evaluation by the DAH indicating that the outer wings are subject to WFD. The root cause of WFD is fatigue cracks manifesting and growing simultaneously at similar structural details and stress levels on the outer wings. Fatigue cracking is increasingly likely as the airplane is being operated and is aging; and without intervention, fatigue cracking of the outer wing could result in reduced structural integrity of the airplane.

Relevant Service Information

We reviewed Lockheed Service Bulletin 382–57–96, dated December 16, 2013. This service bulletin describes procedures for replacing outer wings having serial numbers 3946 through 4541 inclusive, and for replacing manufacturing end product replacement outer wings 14Y series having part numbers 388021–9/-10 with new or certain serviceable outer wings.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or

develop in other products of the same type designs.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between this Proposed AD and the Service Information.''

Differences Between This Proposed AD and the Service Information

Operators should note that Lockheed Service Bulletin 382–57–96, dated December 16, 2013, states that airplanes with more than 30,000 total flight hours on certain outer wings should be grounded until the outer wings are replaced. The manufacturer has informed us that there is a 28-month lead time for obtaining replacement outer wings. We find 30 months after the effective date of this AD for airplanes having outer wings that have accumulated 30,000 total flight hours or more to be an appropriate compliance time to complete outer wing replacement. In developing the compliance time for this action, we considered the degree of urgency associated with addressing the unsafe condition, the maximum interval of time allowable for all affected airplanes to continue to operate without compromising safety, and the availability of required parts.

Explanation of Compliance Time

The compliance time for the replacement specified in this proposed AD for addressing WFD was established to ensure that discrepant structure is replaced before WFD develops in airplanes. Standard inspection techniques cannot be relied on to detect WFD before it becomes a hazard to flight. We will not grant any extensions of the compliance time to complete any AD-mandated service bulletin related to WFD without extensive new data that would substantiate and clearly warrant such an extension.

Costs of Compliance

We estimate that this proposed AD affects 20 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Left and right outer wing replacement	1,500 work-hours × $85 per hour = $127,500	$8,000,000	$8,127,500	$162,550,000

Initial Regulatory Flexibility Analysis

This section presents the initial regulatory flexibility analysis (IRFA) that was prepared for this action. We have reworded and reformatted this analysis for publication in the **Federal Register**.

The Regulatory Flexibility Act of 1980 (Public Law 96–354) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

The FAA finds that this proposed rule would have a significant impact on a substantial number of entities. Therefore, under Section 603(b) of the RFA, the IRFA must address:

- A description of reasons the agency is considering the action;
- A statement of the legal basis and objectives for the proposed rule;
- A description of the record keeping and other compliance requirements of the proposed rule;
- All federal rules that may duplicate, overlap, or conflict with the proposed rule;
- A description and an estimated number of small entities to which the proposed rule will apply; and
- A description of alternatives considered.

The following provides a detailed description of each of the six items specified previously.

1. A Description of Reasons the Agency Is Considering the Action

We are proposing to adopt a new AD for all Lockheed Martin Corporation/ Lockheed Martin Aeronautics Company Model 382, 382B, 382E, 382F, and 382G airplanes because we evaluated all the relevant information and determined the unsafe condition is likely to exist or develop in other products of the same type design. This proposed rule was prompted by an evaluation by the design approval holder (DAH) indicating that the outer wings are subject to WFD. This proposed rule would require replacing certain outer wings with new or certain serviceable outer wings.

2. A Statement of the Legal Basis and Objectives for the Proposed Rule

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority. We propose this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action. The objective of this proposed AD is to prevent fatigue cracking of the outer wing, which has resulted in an accident, and to prohibit exceeding the LOV.

3. A Description of the Record Keeping and Other Compliance Requirements of the Proposed Rule

The agency expects only minimal documentation, reporting, and record-keeping compliance requirements to result from this proposed rule. Every operator (including small businesses and businesses with greater than 1,500

employees) will incur a paperwork burden.

4. All Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

We are unaware that this proposed rule will overlap, duplicate, or conflict with existing Federal rules.

5. A Description and an Estimated Number of Small Entities to Which the Proposed Rule Will Apply

Operators affected by this proposed rule would be required to comply with the AD requirements within 30 months after the effective date of the final rule. The FAA uses current U.S. operators' employment and annual revenue in order to determine the number of operators this proposed rule affects.

To determine the economic impact of this proposed rule on small business operators, the agency began by identifying the affected firms, gathering operational data, and establishing the compliance cost impact. We obtained a list of U.S. operators who would be affected by this proposed rule from the FAA Flight Standards Service National Vital Information Subsystem (NVIS) database and from private fleet data providers. Using information provided by the U.S. Department of Transportation Form 41 filings, the World Aviation Directory & Aerospace Database (WAD), and the Internet, the agency obtained company revenue and employment for many of the operators.

We determined that nine operators could be affected by this proposed rule. Many of these are air cargo operators. Of the nine operators, there are seven that publically reported annual employment and operating revenue data. All seven operators that reported annual employment data are below the Small Business Administration's (SBA) size standard of 1,500 employees for a small business in the air transport industry. Due to the sparse amount of publicly available data on internal company financial and employment statistics for small entities, it is not feasible to identify how many of the remaining carriers would also qualify as small businesses. Based on the publically available data, this proposed rule would have an impact on a substantial number of small entities.

To assess this proposed rule's cost impact to small business operators, we determined the additional cost this rulemaking would add to the seven operators.

We use the average hourly labor cost (including benefits) as a basis to estimate costs for the outer wing replacement of the affected aircraft. In order to estimate the impact on small entities, we sum the incremental costs of this proposed rule, and use that estimate to calculate an average cost per operator. We then use that average to estimate the total cost burden on operators that we identify as meeting the above definition of small entities.

Specifically, we estimate each operator's total compliance cost by multiplying our estimate of the average cost per outer wing replacement by the number of affected aircraft each of the seven air carriers operate that meet the SBA's size standard for a small business of 1,500 employees.

From the summer 2013 edition of the *Airliner Price Guide,* we determined the used retail value of the affected aircraft, which ranges between $1.92 and $2.91 million. In the preamble of this proposed rule, we estimate that it would cost an operator about $8.1 million to replace the outer wing. In other words, this proposed rule would cost between three to four times the retail value of the aircraft.

On the basis of these estimates, we conclude that this proposed rule will have a significant economic impact on a substantial number of small entities.

6. A Description of Alternatives Considered

The FAA considered alternatives as it developed the proposed rule. A discussion of those alternatives follows.

Alternative 1: The Status Quo

The status quo alternative has no compliance costs, but to continue operation of the affected aircraft constitutes a known unsafe condition. Therefore, we rejected this status quo alternative.

Alternative 2: Excluding Certain Small Entities

We considered excluding certain operators from compliance with the proposed rule because they are small entities; however, the affected aircraft operated by small entities could experience WFD, which could result in reduced structural integrity of the airplane that has led to catastrophic accidents. Thus, we did not find this alternative to be acceptable.

Alternative 3: Extending the Final Compliance Date for Small Entities

Extending the compliance date for small entities reduces the costs to small entities over the analysis interval. Under this alternative, we expect that the projected cost of the proposed rule would still be significant for some of the operators studied. As the airplane ages, the wing deteriorates, making a flight less safe. Thus, we also found this alternative to be unacceptable.

Therefore, this rulemaking will have a significant economic impact on a substantial number of small entities. We invite public comments regarding this determination.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

(3) Will not affect intrastate aviation in Alaska, and

(4) Will have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Lockheed Martin Corporation/Lockheed Martin Aeronautics Company: Docket No. FAA–2014–0779; Directorate Identifier 2014–NM–052–AD.

(a) Comments Due Date

We must receive comments by January 15, 2015.

(b) Affected ADs

This AD affects AD 2012–06–09, Amendment 39–16990 (77 FR 21404, April 10, 2012); AD 2011–15–02, Amendment 39–16749 (76 FR 41647, July 15, 2011).

(c) Applicability

This AD applies to all Lockheed Martin Corporation/Lockheed Martin Aeronautics Company Model 382, 382B, 382E, 382F, and 382G airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by an evaluation by the design approval holder indicating that the outer wings are subject to widespread fatigue damage. We are issuing this AD to prevent fatigue cracking of the outer wing, which could result in reduced structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Outer Wing Replacement

For airplanes with outer wings having serial numbers (S/Ns) 3946 through 4541 inclusive, or manufacturing end product (MEP) replacement outer wings 14Y series having part numbers (P/Ns) 388021–9/–10: Before the accumulation of 30,000 total flight hours on the outer wings, or within 30 months after the effective date of this AD, whichever occurs later, except as specified in paragraph (i) of this AD, replace the outer wings as provided in paragraphs (h)(1) and (h)(2) of this AD, as applicable, in accordance with the Accomplishment Instructions of Lockheed Service Bulletin 382–57–96, dated December 16, 2013.

(h) Acceptable Replacement Wings

(1) Outer wings having S/Ns 3946 through 4541 inclusive, and MEP replacement outer wings 14Y series having P/Ns 388021–9/–10, are acceptable for the outer wing replacement required by paragraph (g) of this AD, provided that the replacement outer wing has accumulated less than 30,000 total flight hours. Upon reaching 30,000 total flight hours, the replacement outer wing must be replaced as required by paragraph (g) of this AD.

(2) Outer wings having S/Ns 4542 and subsequent, or all MEP replacement outer wings, except for 14Y series having P/Ns 388021–9/–10, that have accumulated less than 75,000 total flight hours are acceptable for the outer wing replacement required by paragraph (g) of this AD.

Note 1 to paragraph (h) of this AD: Lockheed Service Bulletin 382–57–96, dated December 16, 2013, describes an option to salvage certain system components when replacing an outer wing. An operator may need to recertify compliance with AD 2012–06–09, Amendment 39–16990 (77 FR 21404, April 10, 2012); and AD 2011–15–02, Amendment 39–16749 (76 FR 41647, July 15, 2011); if salvaged components are used in a replacement wing.

(i) Wings With Previous Military Usage

For airplanes that have any wing with previous military usage: Within 30 days after the effective date of this AD, contact the Manager, Atlanta Aircraft Certification Office (ACO), FAA, for a compliance time to accomplish the actions required by paragraph (g) of this AD. For a compliance time to be approved by the Manager, Atlanta ACO, as required by this paragraph, the Manager's approval letter must specifically refer to this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (k)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Related Information

(1) For more information about this AD, Carl Gray, Aerospace Engineer, Airframe Branch, ACE–117A, FAA, Atlanta ACO, 1701 Columbia Avenue, College Park, GA 30337; phone: 404–474–5554; fax: 404–474–5605; email: *carl.w.gray@faa.gov*.

(2) For service information identified in this AD, contact Lockheed Martin Corporation/Lockheed Martin Aeronautics Company, Airworthiness Office, Dept. 6A0M, Zone 0252, Column P–58, 86 S. Cobb Drive, Marietta, GA 30063; telephone 770–494–5444; fax 770–494–5445; email *ams.portal@lmco.com;* Internet *http://www.lockheedmartin.com/ams/tools/TechPubs.html*. You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on November 19, 2014.

Suzanne Masterson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–28304 Filed 11–28–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0780; Directorate Identifier 2014–NM–168–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for The Boeing Company Model 747 airplanes equipped with a main deck side cargo door (MDSCD). This proposed AD was prompted by recent testing that indicates that intermodal containers, when loaded as cargo, under certain flight-load conditions, can shift and impact the adjacent fuselage frames. This proposed AD would require revising the airplane flight manual to incorporate limitations for carrying certain payloads. We are proposing this AD to prevent intermodal containers loaded in the offset method from shifting during flight gust loads and damaging fuselage frames, which could lead to the structural failure of the aft fuselage in flight, and subsequent in-flight breakup of the airplane.

DATES: We must receive comments on this proposed AD by January 15, 2015.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0780; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Steven C. Fox, Senior Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6425; fax: 425–917–6590; email: *steven.fox@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2014–0780; Directorate Identifier 2014–NM–168–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

Intermodal containers are common in the cargo shipping industry and transported by ships, trains, and trucks. The focus of this NPRM is an intermodal container that is nominally 20 feet long, 8 feet wide, and 8.5 feet tall. This nominally sized intermodal container includes the dimensions of an International Organization for Standardization (ISO) container ISO 668–1CC. The intermodal containers themselves do not meet the requirements of FAA Technical Standard Order TSO–C90D, ''Cargo Pallets, Nets and Containers (Unit Load Devices)'' (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgTSO.nsf/0/ba3cb5aeb6d07bec8625792d0052e535/$FILE/TSO_C90_RevD_doc_FINAL_%20RGL_2011%200930.pdf*); the lower surface on these intermodal containers is incompatible with most airplane cargo-loading systems (CLSs). These intermodal containers, however, can be concentrically loaded on an FAA-approved TSO–C90D pallet with the certified net combination and loaded in the center of the airplane, restrained by the CLS or a series of straps connected to the aircraft structure in accordance with the airplane's FAA-approved Weight and Balance Manual procedures for cargo that is not a Unit Load Device (ULD).

The Weight and Balance Manual is part of the Operating Limitations section of the Airplane Flight Manual (AFM). In accordance with 14 CFR 21.41, the Operating Limitations are part of the airplane type certificate and, therefore, can be modified only by changing that certificate; that is, by obtaining an amended or supplemental type certificate. Revisions to the AFM are approved as AFM supplements, and the approval is based on a finding that, with the AFM revisions, the airplane continues to meet the applicable airworthiness standards. Operators are required to comply with the Operating Limitations by 14 CFR 91.9(a).

The FAA has become aware that some operators, both domestic and foreign, are not loading these containers in the center of the airplane, but rather in the standard left and right pallet positions. The 8-foot, 6-inch, height of the intermodal container interferes with the fuselage when loaded in the standard left and right pallet positions, so some operators have been transporting these intermodal containers shifted inboard off of the FAA-approved TSO pallets and attached to the pallet only with a net and/or straps. This method of transport is referred to as the ''offset method.'' The practice of offsetting the intermodal containers results in the certified pallet-net combination having slack in the net by the amount of the offset. FAA observations have found the offset for intermodal containers is as much as 9 inches, with the corresponding 9 inches of slack in the TSO pallet net.

Although additional cargo straps have been used to restrain the intermodal containers to the pallets, the FAA determined that these straps are not effective, and the intermodal container can shift in flight.

In 2013, a U.S. cargo operator requested permission from the FAA to carry intermodal containers on Boeing Model 747 airplanes using the offset method—similar to procedures used by other U.S. and non-U.S. air carriers. Based on the FAA's review of the offset method, it denied the operator's request.

In March 2014, some U.S. cargo operators and Boeing conducted a series of full-scale tests, witnessed by the FAA, to demonstrate that carrying intermodal containers by the offset method could be shown safe and compliant to the applicable regulations. The test procedures were developed by engineers from Boeing and some U.S. cargo operators, and were intended to show compliance for flight loads on Model 747 airplanes only. The results produced CLS failures and/or excessive deflections. The preliminary test results confirmed the FAA's safety concerns.

Testing New Methods

U.S. operators and Boeing conducted additional testing to demonstrate that carrying intermodal containers by the offset method could be shown safe and compliant to the applicable regulations. This testing used methods from National Aerospace Standard (NAS) 3610 with maximum payloads that were reduced from those tested previously. The intent was for Boeing to use the test data to develop an appropriate loading method that could be incorporated into the Boeing 747 Weight and Balance Manual. The certified pallet net was not used because previous testing showed it ineffective in restraining the ISO container as the offset of the container on the pallet introduces slack in the net, with the container essentially free to move laterally in the airplane by the amount of the offset.

Significant engineering resources were applied, and a complex method of strapping installation and procedures and sequence for tightening the straps was developed to preclude the excessive deflections experienced during earlier tests. While a few load cases were successful, some had very small margins (precluding any reduction of the complexity of the nearly 100 straps required). The testing was halted after attempts to substantiate vertical loading repetitively overloaded the forward and aft CLS restraint locks, and the proposed cargo restraining method was deemed unviable.

FAA Observations and Conclusions

FAA engineering from the Transport Airplane Directorate has been extensively involved in the testing of offset loading methods for intermodal containers with the objective to determine and document a safe and compliant methodology that could be the basis for a Boeing 747 Weight and Balance Supplement for airline use

worldwide. Testing to date indicates this objective has not been met.

When positioned in accordance with the Weight and Balance Manual, the intermodal container is secured to the CLS pallet along its entire length by straps and netting. Offsetting the container has the effect of creating slack in the net and straps except at the ends of the container. As a result, when gust loads are encountered, most of the loads are transferred to the locks at the ends of the container and are not shared with the locks in the middle. This uneven loading has the effect of exceeding the structural capability of the locks at the ends of the container. This phenomenon quickly failed the forward and aft CLS locks during vertical testing, as confirmed by both sets of industry testing.

At this time, there is no offset method for restraining intermodal containers that has been demonstrated to be safe and compliant.

Safety Issue

The current practice of carrying an intermodal container by the offset method is not permitted by the Boeing 747 Weight and Balance Manual. A series of tests has verified that an intermodal container, under certain flight-load conditions, can shift in both the outboard and vertical directions. This shift by the intermodal container can damage as many as ten fuselage frames per container position during flight, leading to the structural failure of the aft fuselage in flight, and subsequent in-flight breakup of the airplane.

Normally the FAA does not issue ADs to address non-compliance with existing regulations. But because of the widespread nature of these practices, the FAA has determined that issuing an AD is the most effective means of addressing this unsafe condition.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require revising the Limitations section of the airplane flight manual (AFM) to incorporate limitations on carrying certain payloads.

Costs of Compliance

We estimate that this proposed AD affects 98 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
AFM revision	1 work-hour × $85 per hour = $85	$0	$85	$8,330

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

(3) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2014–0780; Directorate Identifier 2014–NM–168–AD.

(a) Comments Due Date

We must receive comments by January 15, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, 747SP, 747–8F, and 747–8 series airplanes, certificated in any category, equipped with a main deck side cargo door (MDSCD).

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by recent testing that indicates that intermodal containers, when loaded as cargo, under certain flight-load conditions, can shift and impact the adjacent fuselage frames. We are issuing this AD to prevent intermodal containers loaded in the offset method from shifting during flight gust loads and damaging fuselage frames, which could lead to the structural failure of the aft fuselage in flight, and subsequent in-flight breakup of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Revision of Airplane Flight Manual (AFM)

Within 14 days after the effective date of this AD, revise the Operating Limitations section of the FAA-approved AFM to include the information in figure 1 to paragraph (g) of this AD. This may be accomplished by inserting a copy of this AD into the Limitations section of the AFM.

FIGURE 1 TO PARAGRAPH (G) OF THIS AD–AFM REVISION

Unless approved by the Manager of the Seattle Aircraft Certification Office, the carriage of the following payloads is prohibited:
1) Intermodal containers nominally sized at 20 feet long, 8 feet wide, and 8.5 feet tall that are not concentrically loaded on a pallet and restrained to the aircraft in accordance with the FAA-approved Weight and Balance Manual or Supplement.
2) ISO 668-1CC containers that are not concentrically loaded on a pallet and restrained to the aircraft in accordance with the FAA-approved Weight and Balance Manual or Supplement.
Note: Both payloads 1 and 2 may be concentrically loaded on a pallet and netted in accordance with the FAA-approved Weight and Balance Manual and then loaded in the center of the airplane and restrained to the airplane by the approved center loaded cargo restraint system or restrained directly to the airplane, both as defined in the FAA-approved Weight and Balance Manual.

(h) Special Flight Permits

Special flight permits, as described in Section 21.197 and Section 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199), are not allowed if any intermodal container prohibited as specified in figure 1 to paragraph (g) of this AD is on board. For special flight permits, carriage of freight is not allowed.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

For more information about this AD, contact Steven C. Fox, Senior Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6425; fax: 425–917–6590; email: *steven.fox@faa.gov.*

Issued in Renton, Washington, on November 21, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–28303 Filed 11–28–14; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2011–0725, FRL–9919–95–Region–8]

Promulgation of State Implementation Plan Revisions; Infrastructure Requirements for the 1997 and 2006 $PM_{2.5}$, 2008 Lead, 2008 Ozone, and 2010 NO_2 National Ambient Air Quality Standards; South Dakota

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve elements of State Implementation Plan (SIP) revisions from the State of South Dakota to demonstrate the State meets infrastructure requirements of the Clean Air Act (CAA) for the National Ambient Air Quality Standards (NAAQS) promulgated for particulate matter (PM) on July 18, 1997 and October 17, 2006; lead (Pb) on October 15, 2008; ozone on March 12, 2008; and nitrogen dioxide (NO_2) on January 22, 2010. EPA is also proposing to approve SIP revisions the State submitted updating the Prevention of Significant Deterioration (PSD) program and provisions regarding state boards. Section 110(a) of the CAA requires that each state submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by EPA.

DATES: Written comments must be received on or before December 31, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2011–0725, by one of the following methods:

- *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- Email: *fulton.abby@epa.gov.*
- Fax: (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).
- Mail: Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129.
- Hand Delivery: Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129. Such deliveries are only accepted Monday through Friday, 8:00 a.m. to 4:30 p.m., excluding federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R08–OAR–2011–0725. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA, without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to

technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* For additional instructions on submitting comments, go to section I, General Information, of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Abby Fulton, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129. 303–312–6563, *fulton.abby@epa.gov.*

SUPPLEMENTARY INFORMATION:

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The word *Administrator* means or refers to the Administrator of the U.S. Environmental Protection Agency.

(ii) The initials *AERR* mean or refer to Air Emissions Reporting Rule.

(iii) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(iv) The initials *AMNP* mean or refer to Air Monitoring Network Plan.

(v) The initials *ARSD* mean or refer to the Administrative Rules of South Dakota.

(vi) The initials *BACT* mean or refer to Best Available Control Technology.

(vii) The initials *BME* mean or refer to Board of Minerals and Environment.

(viii) The initials *CAIR* mean or refer to the Clean Air Interstate Rule.

(ix) The initials *CBI* mean or refer to confidential business information.

(x) The initials *CSAPR* mean or refer to the Cross-State Air Pollution Rule.

(xi) The words or initials *Department* or *DENR* mean or refer to the Department of Environment and Natural Resources.

(xii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(xiii) The initials *FRM* mean or refer to Federal Reference Method.

(xiv) The initials *GHG* mean or refer to greenhouse gases.

(xv) The initials *NAAQS* mean or refer to national ambient air quality standards.

(xvi) The initials *NEI* mean or refer to the National Emissions Inventory.

(xvii) The initials NO_2 mean or refer to nitrogen dioxide. The 2010 NO_2 NAAQS is expressed as the three year average of the 98th percentile of the annual distribution of daily maximum 1-hour average concentrations.

(xviii) The initials *NSR* mean or refer to new source review.

(xix) The initials *Pb* mean or refer to primary and secondary lead less than or equal to 0.15 micrograms per cubic meter.

(xx) The initials *PM* mean or refer to particulate matter.

(xxi) The initials $PM_{2.5}$ mean or refer to particulate matter with an aerodynamic diameter of less than 2.5 micrometers (fine particulate matter).

(xxii) The initials *ppb* mean or refer to parts per billion.

(xxiii) The initials *ppm* mean or refer to parts per million.

(xxiv) The initials *PSD* mean or refer to Prevention of Significant Deterioration.

(xxv) The initials *SDCL* mean or refer to South Dakota Codified Laws.

(xxvi) The initials *SILs* mean or refer to significant impact level.

(xxvii) The initials *SIP* mean or refer to State Implementation Plan.

(xxviii) The initials *SLAMS* mean or refer to State and Local Air Monitoring Stations.

(xxix) The initials *SMCs* mean or refer to significant monitoring concentrations.

(xxx) The initials *SSM* mean or refer to start-up, shutdown, or malfunction.

(xxxi) The word *State* means or refers to the State of South Dakota.

(xxxii) The initials $\mu g/m^3$ mean or refer to micrograms per cubic meter.

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I. General Information

What should I consider as I prepare my comments for EPA?

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

2. *Tips for preparing your comments.* When submitting comments, remember to:

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

II. Background

On July 18, 1997, EPA promulgated a new 24-hour and annual NAAQS for fine particulate matter ($PM_{2.5}$) (62 FR 38652). More recently, on October 17, 2006, EPA revised the standards for

$PM_{2.5}$, tightening the 24-hour $PM_{2.5}$ standard from 65 micrograms per cubic meter (μg/m³) to 35μg/m³, and retaining the annual $PM_{2.5}$ standard at 15 μg/m³ (71 FR 61144). On March 12, 2008, EPA promulgated a new NAAQS for ozone, revising the levels of the primary and secondary 8-hour ozone standards from 0.08 parts per million (ppm) to 0.075 ppm (73 FR 16436). Subsequently, on October 15, 2008, EPA revised the level of the primary and secondary Pb NAAQS from 1.5 micrograms per cubic meter (μg/m³) to 0.15 μg/m³ (73 FR 66964). On January 22, 2010, EPA promulgated a new 1-hour primary NAAQS for NO_2 at a level of 100 parts per billion (ppb) while retaining the annual standard of 53 ppb. The secondary NO_2 NAAQS remains unchanged at 53 ppb (75 FR 6474, Feb. 9, 2010).

Under sections 110(a)(1) and (2) of the CAA, states are required to submit infrastructure SIPs to ensure their SIPs provide for implementation, maintenance, and enforcement of the NAAQS. These submissions must contain any revisions needed for meeting the applicable SIP requirements of section 110(a)(2), or certifications that their existing SIPs for PM, ozone, Pb, and NO_2 already meet those requirements. EPA highlighted this statutory requirement in an October 2, 2007, guidance document entitled ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 1997 8-hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards'' (2007 Memo). On September 25, 2009, EPA issued an additional guidance document pertaining to the 2006 $PM_{2.5}$ NAAQS entitled ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 2006 24-Hour Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS)'' (2009 Memo), followed by the October 14, 2011, ''Guidance on Infrastructure SIP Elements Required Under Sections 110(a)(1) and (2) for the 2008 Lead (Pb) National Ambient Air Quality Standards (NAAQS)'' (2011 Memo). Most recently, EPA issued ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and (2)'' on September 13, 2013 (2013 Memo).

III. What is the scope of this Rulemaking?

EPA is acting upon the SIP submissions from South Dakota that address the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the1997 and 2006 $PM_{2.5}$, 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS. The requirement for states to make a SIP submission of this type arises out of CAA section 110(a)(1). Pursuant to section 110(a)(1), states must make SIP submissions ''within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof),'' and these SIP submissions are to provide for the ''implementation, maintenance, and enforcement'' of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that ''[e]ach such plan'' submission must address.

EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of CAA sections 110(a)(1) and 110(a)(2) as ''infrastructure SIP'' submissions. Although the term ''infrastructure SIP'' does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submission from submissions that are intended to satisfy other SIP requirements under the CAA, such as ''nonattainment SIP'' or ''attainment plan SIP'' submissions to address the nonattainment planning requirements of part D of title I of the CAA; ''regional haze SIP'' submissions required by EPA rule to address the visibility protection requirements of CAA section 169A; and nonattainment new source review (NSR) permit program submissions to address the permit requirements of CAA, title I, part D.

Section 110(a)(1) addresses the timing and general requirements for infrastructure SIP submissions, and section 110(a)(2) provides more details concerning the required contents of these submissions. The list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive program provisions, and some of which pertain to requirements for both authority and substantive program provisions.[1] EPA therefore believes that while the timing requirement in section 110(a)(1) is unambiguous, some of the other statutory provisions are ambiguous. In particular, EPA believes that the list of required elements for infrastructure SIP submissions provided in section 110(a)(2) contains ambiguities concerning what is required for inclusion in an infrastructure SIP submission.

The following examples of ambiguities illustrate the need for EPA to interpret some section 110(a)(1) and section 110(a)(2) requirements with respect to infrastructure SIP submissions for a given new or revised NAAQS. One example of ambiguity is section 110(a)(2) requires that ''each'' SIP submission must meet the list of requirements therein, while EPA has long noted that this literal reading of the statute is internally inconsistent and would create a conflict with the nonattainment provisions in part D of title I of the CAA, which specifically address nonattainment SIP requirements.[2] Section 110(a)(2)(I) pertains to nonattainment SIP requirements and part D addresses when attainment plan SIP submissions to address nonattainment area requirements are due. For example, section 172(b) requires EPA to establish a schedule for submission of such plans for certain pollutants when the Administrator promulgates the designation of an area as nonattainment, and section 107(d)(1)(B) allows up to two years, or in some cases three years, for such designations to be promulgated.[3] This ambiguity illustrates that rather than apply all the stated requirements of section 110(a)(2) in a strict literal sense, EPA must determine which provisions of section 110(a)(2) are applicable for a particular infrastructure SIP submission.

Another example of ambiguity within sections 110(a)(1) and 110(a)(2) with respect to infrastructure SIPs pertains to whether states must meet all of the infrastructure SIP requirements in a single SIP submission, and whether EPA must act upon such SIP submission in a single action. Although section 110(a)(1) directs states to submit ''a

[1] For example: Section 110(a)(2)(E)(i) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; section 110(a)(2)(C) provides that states must have a SIP-approved program to address certain sources as required by part C of title I of the CAA; and section 110(a)(2)(G) provides that states must have legal authority to address emergencies as well as contingency plans that are triggered in the event of such emergencies.

[2] See, *e.g.*, ''Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_X SIP Call; Final Rule,'' 70 FR 25162, at 25163–65 (May 12, 2005) (explaining relationship between timing requirement of section 110(a)(2)(D) versus section 110(a)(2)(I)).

[3] EPA notes that this ambiguity within section 110(a)(2) is heightened by the fact that various subparts of part D set specific dates for submission of certain types of SIP submissions in designated nonattainment areas for various pollutants. Note, *e.g.*, that section 182(a)(1) provides specific dates for submission of emissions inventories for the ozone NAAQS. Some of these specific dates are necessarily later than three years after promulgation of the new or revised NAAQS.

plan'' to meet these requirements, EPA interprets the CAA to allow states to make multiple SIP submissions separately addressing infrastructure SIP elements for the same NAAQS. If states elect to make such multiple SIP submissions to meet the infrastructure SIP requirements, EPA can elect to act on such submissions either individually or in a larger combined action.[4] Similarly, EPA interprets the CAA to allow it to take action on the individual parts of one larger, comprehensive infrastructure SIP submission for a given NAAQS without concurrent action on the entire submission. For example, EPA has sometimes elected to act at different times on various elements and sub-elements of the same infrastructure SIP submission.[5]

Ambiguities within sections 110(a)(1) and 110(a)(2) may also arise with respect to infrastructure SIP submission requirements for different NAAQS. Thus, EPA notes that not every element of section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAQS. The states' attendant infrastructure SIP submissions for each NAAQS therefore could be different. For example, the monitoring requirements that a state might need to meet in its infrastructure SIP submission for purposes of section 110(a)(2)(B) could be very different for different pollutants because the content and scope of a state's infrastructure SIP submission to meet this element might be very different for an entirely new NAAQS than for a minor revision to an existing NAAQS.[6]

EPA notes that interpretation of section 110(a)(2) is also necessary when EPA reviews other types of SIP submissions required under the CAA. Therefore, as with infrastructure SIP submissions, EPA also has to identify and interpret the relevant elements of section 110(a)(2) that logically apply to these other types of SIP submissions. For example, section 172(c)(7) requires that attainment plan SIP submissions required by part D have to meet the ''applicable requirements'' of section 110(a)(2). Thus, for example, attainment plan SIP submissions must meet the requirements of section 110(a)(2)(A) regarding enforceable emission limits and control measures and section 110(a)(2)(E)(i) regarding air agency resources and authority. By contrast, it is clear that attainment plan SIP submissions required by part D would not need to meet the portion of section 110(a)(2)(C) that pertains to the PSD program required in part C of title I of the CAA, because PSD does not apply to a pollutant for which an area is designated nonattainment and thus subject to part D planning requirements. As this example illustrates, each type of SIP submission may implicate some elements of section 110(a)(2) but not others.

Given the potential for ambiguity in some of the statutory language of section 110(a)(1) and section 110(a)(2), EPA believes that it is appropriate to interpret the ambiguous portions of section 110(a)(1) and section 110(a)(2) in the context of acting on a particular SIP submission. In other words, EPA assumes that Congress could not have intended that each and every SIP submission, regardless of the NAAQS in question or the history of SIP development for the relevant pollutant, would meet each of the requirements, or meet each of them in the same way. Therefore, EPA has adopted an approach under which it reviews infrastructure SIP submissions against the list of elements in section 110(a)(2), but only to the extent each element applies for that particular NAAQS.

Historically, EPA has elected to use guidance documents to make recommendations to states for infrastructure SIPs, in some cases conveying needed interpretations on newly arising issues and in some cases conveying interpretations that have already been developed and applied to individual SIP submissions for particular elements.[7] EPA's 2013 Memo was developed to provide states with up-to-date guidance for infrastructure SIPs for any new or revised NAAQS. Within this guidance, EPA describes the duty of states to make infrastructure SIP submissions to meet basic structural SIP requirements within three years of promulgation of a new or revised NAAQS. EPA also made recommendations about many specific subsections of section 110(a)(2) that are relevant in the context of infrastructure SIP submissions.[8] The guidance also discusses the substantively important issues that are germane to certain subsections of section 110(a)(2). Significantly, EPA interprets sections 110(a)(1) and 110(a)(2) such that infrastructure SIP submissions need to address certain issues and need not address others. Accordingly, EPA reviews each infrastructure SIP submission for compliance with the applicable statutory provisions of section 110(a)(2), as appropriate.

As an example, section 110(a)(2)(E)(ii) is a required element of section 110(a)(2) for infrastructure SIP submissions. Under this element, a state must meet the substantive requirements of section 128, which pertain to state boards that approve permits or enforcement orders and heads of executive agencies with similar powers. Thus, EPA reviews infrastructure SIP submissions to ensure that the state's SIP appropriately addresses the requirements of section 110(a)(2)(E)(ii) and section 128. The 2013 Memo explains EPA's interpretation that there may be a variety of ways by which states can appropriately address these substantive statutory requirements, depending on the structure of an individual state's permitting or enforcement program (*e.g.,* whether permits and enforcement orders are approved by a multi-member board or by a head of an executive agency). However they are addressed by the state, the substantive requirements of

[4] See, e.g., ''Approval and Promulgation of Implementation Plans; New Mexico; Revisions to the New Source Review (NSR) State Implementation Plan (SIP); Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) Permitting,'' (78 FR 4339, Jan. 22, 2013) (EPA's final action approving the structural PSD elements of the New Mexico SIP submitted by the State separately to meet the requirements of EPA's 2008 $PM_{2.5}$ NSR rule), and ''Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Infrastructure and Interstate Transport Requirements for the 2006 p.m.2.5 NAAQS,'' (78 FR 4337, Jan. 22, 2013) (EPA's final action on the infrastructure SIP for the 2006 $PM_{2.5}$ NAAQS).

[5] On December 14, 2007, the State of Tennessee, through the Tennessee Department of Environment and Conservation, made a SIP revision to EPA demonstrating that the State meets the requirements of sections 110(a)(1) and (2). EPA proposed action for infrastructure SIP elements (C) and (J) on January 23, 2012 (77 FR 3213) and took final action on March 14, 2012 (77 FR 14976). On April 16, 2012 (77 FR 22533) and July 23, 2012 (77 FR 42997), EPA took separate proposed and final actions on all other section 110(a)(2) infrastructure SIP elements of Tennessee's December 14, 2007 submittal.

[6] For example, implementation of the 1997 $PM_{2.5}$ NAAQS required the deployment of a system of new monitors to measure ambient levels of that new indicator species for the new NAAQS.

[7] EPA notes, however, that nothing in the CAA requires EPA to provide guidance or to promulgate regulations for infrastructure SIP submissions. The CAA directly applies to states and requires the submission of infrastructure SIP submissions, regardless of whether or not EPA provides guidance or regulations pertaining to such submissions. EPA elects to issue such guidance in order to assist states, as appropriate.

[8] EPA's September 13, 2013, guidance did not make recommendations with respect to infrastructure SIP submissions to address section 110(a)(2)(D)(i)(I). EPA issued the guidance shortly after the U.S. Supreme Court agreed to review the D.C. Circuit decision in *EME Homer City,* 696 F.3d 7 (D.C. Cir. 2012) which had interpreted the requirements of section 110(a)(2)(D)(i)(I). In light of the uncertainty created by ongoing litigation, EPA elected not to provide additional guidance on the requirements of section 110(a)(2)(D)(i)(I) at that time. As the guidance is neither binding nor required by statute, whether EPA elects to provide guidance on a particular section has no impact on a state's CAA obligations.

section 128 are necessarily included in EPA's evaluation of infrastructure SIP submissions because section 110(a)(2)(E)(ii) explicitly requires the state satisfy the provisions of section 128.

As another example, EPA's review of infrastructure SIP submissions with respect to the PSD program requirements in sections 110(a)(2)(C), (D)(i)(II), and (J) focuses upon the structural PSD program requirements contained in part C and EPA's PSD regulations. Structural PSD program requirements include provisions necessary for the PSD program to address all regulated sources and NSR pollutants, including greenhouse gases (GHGs). By contrast, structural PSD program requirements do not include provisions that are not required under EPA's regulations at 40 CFR 51.166 but are merely available as an option for the state, such as the option to provide grandfathering of complete permit applications with respect to the 2012 $PM_{2.5}$ NAAQS. Accordingly, the latter optional provisions are types of provisions EPA considers irrelevant in the context of an infrastructure SIP action.

For other section 110(a)(2) elements, however, EPA's review of a state's infrastructure SIP submission focuses on assuring that the state's SIP meets basic structural requirements. For example, section 110(a)(2)(C) includes, *inter alia,* the requirement that states have a program to regulate minor new sources. Thus, EPA evaluates whether the state has an EPA approved minor NSR program and whether the program addresses the pollutants relevant to that NAAQS. In the context of acting on an infrastructure SIP submission, however, EPA does not think it is necessary to conduct a review of each and every provision of a state's existing minor source program (*i.e.,* already in the existing SIP) for compliance with the requirements of the CAA and EPA's regulations that pertain to such programs.

With respect to certain other issues, EPA does not believe that an action on a state's infrastructure SIP submission is necessarily the appropriate type of action in which to address possible deficiencies in a state's existing SIP. These issues include: (i) Existing provisions related to excess emissions from sources during periods of startup, shutdown, or malfunction (SSM) that may be contrary to the CAA and EPA's policies addressing such excess emissions; (ii) existing provisions related to ''director's variance'' or ''director's discretion'' that may be contrary to the CAA because they purport to allow revisions to SIP-approved emissions limits while limiting public process or not requiring further approval by EPA; and (iii) existing provisions for PSD programs that may be inconsistent with current requirements of EPA's ''Final NSR Improvement Rule,'' 67 FR 80186, Dec. 31, 2002, as amended by 72 FR 32526, June 13, 2007. (''NSR Reform''). Thus, EPA believes it may approve an infrastructure SIP submission without scrutinizing the totality of the existing SIP for such potentially deficient provisions and may approve the submission even if it is aware of such existing provisions.[9] It is important to note that EPA's approval of a state's infrastructure SIP submission should not be construed as explicit or implicit re-approval of any existing potentially deficient provisions that relate to the three specific issues just described.

EPA's approach to review of infrastructure SIP submissions is to identify the CAA requirements that are logically applicable to that submission. EPA believes that this approach to the review of a particular infrastructure SIP submission is appropriate, because it would not be reasonable to read the general requirements of section 110(a)(1) and the list of elements in 110(a)(2) as requiring review of each and every provision of a state's existing SIP against all requirements in the CAA and EPA regulations merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts. These provisions, while not fully up-to-date, nevertheless may not pose a significant problem for the purposes of ''implementation, maintenance, and enforcement'' of a new or revised NAAQS when EPA evaluates adequacy of the infrastructure SIP submission. EPA believes that a better approach is for states and EPA to focus attention on those elements of section 110(a)(2) of the CAA most likely to warrant a specific SIP revision due to the promulgation of a new or revised NAAQS or other factors.

For example, the 2013 Memo gives simpler recommendations with respect to carbon monoxide than other NAAQS pollutants to meet the visibility requirements of section 110(a)(2)(D)(i)(II), because carbon monoxide does not affect visibility. As a result, an infrastructure SIP submission for any future new or revised NAAQS for carbon monoxide need only state this fact in order to address the visibility prong of section 110(a)(2)(D)(i)(II).

Finally, EPA believes its approach with respect to infrastructure SIP requirements is based on a reasonable reading of sections 110(a)(1) and 110(a)(2) because the CAA provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow EPA to take appropriately tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a ''SIP call'' whenever the agency determines that a state's SIP is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or to otherwise comply with the CAA.[10] Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions.[11] Significantly, EPA's determination that an action on a state's infrastructure SIP submission is not the appropriate time and place to address all potential existing SIP deficiencies does not preclude EPA's subsequent reliance on provisions in section 110(a)(2) as part of the basis for action to correct those deficiencies at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on an infrastructure SIP submission, EPA believes that section 110(a)(2)(A) may be among the statutory bases that EPA relies upon in the course of addressing

[9] By contrast, EPA notes that if a state were to include a new provision in an infrastructure SIP submission that contained a legal deficiency, such as a new exemption for excess emissions during SSM events, then EPA would need to evaluate that provision for compliance against the rubric of applicable CAA requirements in the context of the action on the infrastructure SIP.

[10] For example, EPA issued a SIP call to Utah to address specific existing SIP deficiencies related to the treatment of excess emissions during SSM events. See ''Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revisions,'' 74 FR 21639, April 18, 2011.

[11] EPA has used this authority to correct errors in past actions on SIP submissions related to PSD programs. See ''Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule,'' 75 FR 82536, Dec. 30, 2010. EPA has previously used its authority under CAA section 110(k)(6) to remove numerous other SIP provisions that the Agency determined it had approved in error. See, *e.g.,* 61 FR 38664, July 25, 1996 and 62 FR 34641, June 27, 1997 (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); 69 FR 67062, Nov. 16, 2004 (corrections to California SIP); and 74 FR 57051, Nov. 3, 2009 (corrections to Arizona and Nevada SIPs).

such deficiency in a subsequent action.[12]

IV. What infrastructure elements are required under Sections 110(a)(1) and (2)?

CAA section 110(a)(1) provides the procedural and timing requirements for SIP submissions after a new or revised NAAQS is promulgated. Section 110(a)(2) lists specific elements the SIP must contain or satisfy. These infrastructure elements include requirements such as modeling, monitoring, and emissions inventories, which are designed to assure attainment and maintenance of the NAAQS. The elements that are the subject of this action are listed below.

- 110(a)(2)(A): Emission limits and other control measures.
- 110(a)(2)(B): Ambient air quality monitoring/data system.
- 110(a)(2)(C): Program for enforcement of control measures.
- 110(a)(2)(D): Interstate transport.
- 110(a)(2)(E): Adequate resources and authority, conflict of interest, and oversight of local governments and regional agencies.
- 110(a)(2)(F): Stationary source monitoring and reporting.
- 110(a)(2)(G): Emergency powers.
- 110(a)(2)(H): Future SIP revisions.
- 110(a)(2)(J): Consultation with government officials; public notification; and PSD and visibility protection.
- 110(a)(2)(K): Air quality modeling/data.
- 110(a)(2)(L): Permitting fees.
- 110(a)(2)(M): Consultation/participation by affected local entities.

A detailed discussion of each of these elements is contained in the next section.

Two elements identified in section 110(a)(2) are not governed by the three year submission deadline of section 110(a)(1) and are therefore not addressed in this action. These elements relate to part D of Title I of the CAA, and submissions to satisfy them are not due within three years after promulgation of a new or revised NAAQS, but rather are due at the same time nonattainment area plan requirements are due under section 172. The two elements are: (1) Section 110(a)(2)(C) to the extent it refers to permit programs (known as ''nonattainment NSR'') required under part D, and (2) section 110(a)(2)(I), pertaining to the nonattainment planning requirements of part D. As a result, this action does not address infrastructure elements related to the nonattainment NSR portion of section 110(a)(2)(C) or related to 110(a)(2)(I). Furthermore, EPA interprets the CAA section 110(a)(2)(J) provision on visibility as not being triggered by a new NAAQS because the visibility requirements in part C, title 1 of the CAA are not changed by a new NAAQS.

V. How did South Dakota address the infrastructure elements of Sections 110(a)(1) and (2)?

The South Dakota Department of Environment and Natural Resources (DENR) submitted certifications of South Dakota's infrastructure SIP for the 1997 and 2006 $PM_{2.5}$ NAAQS on May 20, 2008, and March 4, 2011, respectively; the 2008 Pb NAAQS on October 10, 2012; the 2008 ozone NAAQS on May 21, 2013; and the 2010 NO_2 NAAQS October 23, 2013. South Dakota's infrastructure certifications demonstrate how the State, where applicable, has plans in place that meet the requirements of section 110 for the 1997 and 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS. These plans reference the current Administrative Rules of South Dakota (ARSD) and South Dakota Codified Laws (SDCL). These submittals are available within the electronic docket for today's proposed action at *www.regulations.gov.* The ARSD and SDCL referenced in the submittals are publicly available at *http://legis.sd.gov/rules/RulesList.aspx* and *http://legis.sd.gov/Statutes/Codified_Laws/default.aspx.* South Dakota's SIP, air pollution control regulations and statutes that have been previously approved by EPA and incorporated into the South Dakota SIP can be found at 40 CFR 52.2170.

VI. Analysis of the State Submittals

1. Emission limits and other control measures: Section 110(a)(2)(A) requires SIPs to include enforceable emission limitations and other control measures, means, or techniques (including economic incentives such as fees, marketable permits, and auctions of emissions rights), as well as schedules and timetables for compliance as may be necessary or appropriate to meet the applicable requirements of this Act.

Multiple SIP-approved State air quality regulations within the ARSD and cited in South Dakota's certifications provide enforceable emission limitations and other control measures, means of techniques, schedules for compliance, and other related matters necessary to meet the requirements of the CAA section 110(a)(2)(A) for the 1997 and 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS, subject to the following clarifications.

First, this infrastructure element does not require the submittal of regulations or emission limitations developed specifically for attaining the 1997 and 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS. Furthermore, South Dakota has no areas designated as nonattainment for the 1997 and 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS. South Dakota's certifications (contained within this docket) generally listed provisions within its SIP which regulate pollutants through various programs, including major and minor source permit programs. This suffices, in the case of South Dakota, to meet the requirements of section 110(a)(2)(A) for the 1997 and 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

Second, as previously discussed, EPA is not proposing to approve or disapprove any existing state rules with regard to director's discretion or variance provisions. A number of states have such provisions which are contrary to the CAA and existing EPA guidance (52 FR 45109, Nov. 24, 1987), and the agency plans to take action in the future to address such state regulations. In the meantime, EPA encourages any state having a director's discretion or variance provision which is contrary to the CAA and EPA guidance to take steps to correct the deficiency as soon as possible.

Finally, in this action, EPA is also not proposing to approve or disapprove any existing state provision with regard to excess emissions during SSM of operations at a facility. A number of states have SSM provisions which are contrary to the CAA and existing EPA guidance[13] and the agency is addressing such state regulations separately (78 FR 12460, Feb. 22, 2013).

2. Ambient air quality monitoring/data system: Section 110(a)(2)(B) requires SIPs to provide for establishment and operation of appropriate devices, methods, systems, and procedures necessary to ''(i) monitor, compile, and analyze data on ambient air quality, and (ii) upon

[12] See, *e.g.,* EPA's disapproval of a SIP submission from Colorado on the grounds that it would have included a director's discretion provision inconsistent with CAA requirements, including section 110(a)(2)(A). See, *e.g.,* 75 FR 42342 at 42344, July 21, 2010 (proposed disapproval of director's discretion provisions); 76 FR 4540, Jan. 26, 2011 (final disapproval of such provisions).

[13] Steven Herman, Assistant Administrator for Enforcement and Compliance Assurance, and Robert Perciasepe, Assistant Administrator for Air and Radiation, Memorandum to EPA Air Division Directors, ''State Implementation Plans (SIPs): Policy Regarding Emissions During Malfunctions, Startup, and Shutdown.'' (September 20, 1999).

request, make such data available to the Administrator.''

Under ARSD 74:36:02, the DENR operates a network of air monitoring sites. EPA approved South Dakota's DENR 2013 Ambient Air Monitoring Network Plan (AMNP) on December 31, 2013 [14]. The State of South Dakota submits data to EPA's Air Quality System database in accordance with the deadlines in 40 CFR 58.16. South Dakota's air monitoring programs and data systems meet the requirements of CAA section 110(a)(2)(B) for the 1997 and 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

3. Program for enforcement of control measures: Section 110(a)(2)(C) requires SIPs to include a program to provide for the enforcement of the measures described in subparagraph (A), and regulation of the modification and construction of any stationary source within the areas covered by the plan as necessary to assure NAAQS are achieved, including a permit program as required in parts C and D.

To generally meet the requirements of section 110(a)(2)(C), the State is required to have SIP-approved PSD, nonattainment NSR, and minor NSR permitting programs adequate to implement the 1997 and 2006 $PM_{2.5}$, 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS. As explained elsewhere in this action, EPA is not evaluating nonattainment related provisions, such as the nonattainment NSR program required by part D of the Act. EPA is evaluating the State's PSD program as required by part C of the Act, and the State's minor NSR program as required by 110(a)(2)(C).

PSD Requirements

With respect to elements (C) and (J), EPA interprets the CAA to require each state to make an infrastructure SIP submission for a new or revised NAAQS that demonstrates that the air agency has a complete PSD permitting program meeting the current requirements for all regulated NSR pollutants. The requirements of element (D)(i)(II) may also be satisfied by demonstrating the air agency has a complete PSD permitting program correctly addressing all regulated NSR pollutants. South Dakota has shown that it currently has a PSD program in place that covers all regulated NSR pollutants, including GHGs.

South Dakota implements the PSD program by, for the most part, incorporating by reference the federal PSD program as it existed on a specific date. The State periodically updates the PSD program by revising the date of incorporation by reference and submitting the change as a SIP revision. As a result, the SIP revisions generally reflect changes to PSD requirements that EPA has promulgated prior to the revised date of incorporation by reference.

On June 30, 2011, we approved a revision to the South Dakota PSD program that addressed the PSD requirements of the Phase 2 Ozone Implementation Rule promulgated in 2005 (76 FR 43912, July 22, 2011). As a result, the approved South Dakota PSD program meets current requirements for ozone.

On June 23, 2014, the United States Supreme Court issued a decision addressing the application of PSD permitting requirements to GHG emissions, *Utility Air Regulatory Group* v. *Environmental Protection Agency,* 134 S. Ct. 2427. The Supreme Court said that EPA may not treat GHGs as an air pollutant for purposes of determining whether a source is a major source required to obtain a PSD permit. The Court also said that EPA could continue to require that PSD permits, otherwise required based on emissions of pollutants other than GHGs, contain limitations on GHG emissions based on the application of Best Available Control Technology (BACT). In order to act consistently with its understanding of the Court's decision pending further judicial action to effectuate the decision, EPA is not continuing to apply EPA regulations that would require that SIPs include permitting requirements that the Supreme Court found impermissible. Specifically, EPA is not applying the requirement that a state's SIP-approved PSD program require that sources obtain PSD permits when GHGs are the only pollutant (i) that the source emits or has the potential to emit above the major source thresholds, or (ii) for which there is a significant emissions increase and a significant net emissions increase from a modification (*e.g.,* 40 CFR 51.166(b)(48)(v)). EPA anticipates a need to revise federal PSD rules in light of the Supreme Court opinion. In addition, EPA anticipates that many states will revise their existing SIP-approved PSD programs in light of the Supreme Court's decision. The timing and content of subsequent EPA actions with respect to EPA regulations and state PSD program approvals are expected to be informed by additional legal process before the United States Court of Appeals for the District of Columbia Circuit. At this juncture, EPA is not expecting states to have revised their PSD programs for purposes of infrastructure SIP submissions and is only evaluating such submissions to assure that the state's program correctly addresses GHGs consistent with the Supreme Court's decision.

At present, EPA has determined that South Dakota's SIP is sufficient to satisfy elements (C), (D)(i)(II), and (J) with respect to GHGs because the PSD permitting program previously approved by EPA into the SIP continues to require that PSD permits (otherwise required based on emissions of pollutants other than GHGs) contain limitations on GHG emissions based on the application of BACT. Although the approved South Dakota PSD permitting program may currently contain provisions that are no longer necessary in light of the Supreme Court decision, this does not render the infrastructure SIP submission inadequate to satisfy elements (C), (D)(i)(II), and (J). The SIP contains the necessary PSD requirements at this time, and the application of those requirements is not impeded by the presence of other previously-approved provisions regarding the permitting of sources of GHGs that EPA does not consider necessary at this time in light of the Supreme Court decision. Accordingly, the Supreme Court decision does not affect EPA's proposed approval of South Dakota's infrastructure SIP as to the requirements of elements (C), (D)(i)(II), and (J).

Finally, we evaluate the PSD program with respect to current requirements for $PM_{2.5}$. In particular, on May 16, 2008, EPA promulgated the rule, ''Implementation of the New Source Review Program for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)'' (73 FR 28321) and on October 20, 2010, EPA promulgated the rule, ''Prevention of Significant Deterioration (PSD) for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC)'' (75 FR 64864). EPA regards adoption of these $PM_{2.5}$ rules as a necessary requirement when assessing a PSD program for the purposes of element (C).

On January 4, 2013, the U.S. Court of Appeals, in *Natural Resources Defense Council* v. *EPA,* 706 F.3d 428 (D.C. Cir.), issued a judgment that remanded EPA's 2007 and 2008 rules implementing the 1997 $PM_{2.5}$ NAAQS. The court ordered EPA to ''repromulgate these rules pursuant to Subpart 4 consistent with this opinion.'' *Id.* at 437. Subpart 4 of

[14] Currently ambient air monitoring for lead is not conducted or planned because past monitoring and past and current emissions inventories indicate low potential lead concentrations in the State (see page 24 of the 2013 South Dakota AMNP at *http://denr.sd.gov/des/aq/aqnews/Ann%20plan%202013.pdf*).

part D, Title 1 of the CAA establishes additional provisions for PM nonattainment areas.

The 2008 implementation rule addressed by the court decision, ''Implementation of New Source Review (NSR) Program for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$),'' (73 FR 28321, May 16, 2008), promulgated NSR requirements for implementation of $PM_{2.5}$ in nonattainment areas (nonattainment NSR) and attainment/unclassifiable areas (PSD). As the requirements of Subpart 4 only pertain to nonattainment areas, EPA does not consider the portions of the 2008 Implementation rule that address requirements for $PM_{2.5}$ attainment and unclassifiable areas to be affected by the court's opinion. Moreover, EPA does not anticipate the need to revise any PSD requirements promulgated in the 2008 Implementation rule in order to comply with the court's decision. Accordingly, EPA's proposed approval of South Dakota's infrastructure SIP as to elements C or J with respect to the PSD requirements promulgated by the 2008 Implementation rule does not conflict with the court's opinion.

The Court's decision with respect to the nonattainment NSR requirements promulgated by the 2008 Implementation rule also does not affect EPA's action on the present infrastructure action. EPA interprets the Act to exclude nonattainment area requirements, including requirements associated with a nonattainment NSR program, from infrastructure SIP submissions due three years after adoption or revision of a NAAQS. Instead, these elements are typically referred to as nonattainment SIP or attainment plan elements, which would be due by the dates statutorily prescribed under subpart 2 through 5 under part D, extending as far as 10 years following designations for some elements.

The second PSD requirement for $PM_{2.5}$ is contained in EPA's October 20, 2010 rule, ''Prevention of Significant Deterioration (PSD) for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC)'' (75 FR 64864). EPA regards adoption of the $PM_{2.5}$ increments as a necessary requirement when assessing a PSD program for the purposes of element (C).

On July 22, 2011, we approved revisions to ARSD Chapter 74:36:09 that adopted by reference federal provisions of 40 CFR part 52, section 21, as they existed on July 1, 2009 (76 FR 43912, July 22, 2011). As July 1, 2009 is after the effective date of the 2008 $PM_{2.5}$ Implementation Rule, 76 FR 43912 incorporated the requirements of the 2008 $PM_{2.5}$ Implementation Rule; specifically, 40 CFR 52.21(b)(23)(i) and 52.21(b)(50). On July 29, 2013, the State submitted revisions amending the ARSD pertaining to the issuance of South Dakota air quality permits. On June 27, 2014, we acted on two pieces from the July 29, 2013 submittal (see 79 FR 36419) which included the removal of ARSD Chapter 74:36:04:03:01 (Minor Source Operating Permit Variance) and revisions to ARSD Chapter 74:36:10 (New Source Review). The July 29, 2013, submittal also included revisions to ARSD Chapter 74:36:09 (Prevention of Significant Deterioration) which we are acting on in this action. The revision adopted by reference federal provisions of 40 CFR part 52, section 21, as they existed on July 1, 2012. As July 1, 2012 is after the effective date of the 2010 $PM_{2.5}$ Increment Rule, the revisions to ARSD 74:36:09 as submitted on July 29, 2013, incorporate the requirements of the 2010 $PM_{2.5}$ Increment Rule; specifically, 40 CFR 52.21(b)(14)(i), (ii), (iii), (b)(15)(i), (ii), and paragraph (c). We propose to approve the necessary portions of the July 29, 2013 submission to reflect the requirements of the 2010 $PM_{2.5}$ Increment Rule. We are not proposing to act on any other portions of the July 29, 2013 submittal, including the incorporation by reference of SILs and SMCs for $PM_{2.5}$.

With these proposed revisions, South Dakota's SIP-approved PSD program will meet current requirements for $PM_{2.5}$. As a result, EPA is proposing to approve South Dakota's infrastructure SIP for the 1997 and 2006 $PM_{2.5}$, 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS with respect to the requirement in section 110(a)(2)(C) to include a permit program in the SIP as required by part C of the Act.

Minor NSR

The State has a SIP-approved minor NSR program, adopted under section 110(a)(2)(C) of the Act. The minor NSR program was originally approved by EPA on September 6, 1995 (60 FR 46222). Since approval of the minor NSR program, the State and EPA have relied on the program to assure that new and modified sources not captured by the major NSR permitting programs do not interfere with attainment and maintenance of the NAAQS. Additionally, EPA is not proposing to approve or disapprove any state rules with regard to the NSR Reform requirements because they are outside the scope of this action. EPA's recent action taken on changes to South Dakota's minor source NSR program (79 FR 36419, June 27, 2014) does not impact the approvability of Section 110(a)(2)(C) in this action.

EPA is proposing to approve South Dakota's infrastructure SIP for the 1997 and 2006 $PM_{2.5}$, 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS with respect to the general requirement in section 110(a)(2)(C) to include a program in the SIP that regulates the modification and construction of any stationary source as necessary to assure that the NAAQS are achieved.

4. Interstate Transport: Section 110(a)(2)(D)(i) is subdivided into four ''prongs,'' two under 110(a)(2)(D)(i)(I) and two under 110(a)(2)(D)(i)(II). The two prongs under 110(a)(2)(D)(i)(I) require SIPs to contain adequate provisions to prohibit emissions that (prong 1) contribute significantly to nonattainment in any other state with respect to any such national primary or secondary NAAQS, and (prong 2) interfere with maintenance by any other state with respect to the same NAAQS. The two prongs under 110(a)(2)(D)(i)(II) require SIPs to contain adequate provisions to prohibit emissions that interfere with measures required to be included in the applicable implementation plan for any other state under part C (prong 3) to prevent significant deterioration of air quality or (prong 4) to protect visibility.

We are proposing action on all four interstate transport prongs for the 2006 $PM_{2.5}$, 2008 Pb, and 2010 NO_2 NAAQS in this rulemaking. We are not acting on the requirements of section 110(a)(2)(D)(i)(I) (prongs 1 and 2) for the 2008 ozone NAAQS in this proposed rulemaking and will act on these requirements in a separate action, but are proposing to approve prongs 3 and 4 for the 2008 ozone NAAQS with this action. EPA approved all four interstate transport requirements of section 110(a)(2)(D)(i) for the 1997 $PM_{2.5}$ NAAQS in a direct final rulemaking on May 8, 2008 (73 FR 26019).

a. Prong 1 (Significant Contribution to Nonattainment) and 2 (Interference With Maintenance)

2006 $PM_{2.5}$ NAAQS

EPA has previously addressed the requirements of CAA section 110(a)(2)(D)(i)(I) in past regulatory actions.[15] EPA published the final Cross-State Air Pollution Rule (CSAPR) to address the first two elements of CAA section 110(a)(2)(D)(i)(I) in the eastern portion of the United States with respect

[15] *See* NO_X SIP Call (63 FR 57371, Oct. 27, 1998); Clean Air Interstate Rule (CAIR) (70 FR 25172, May 12, 2005); and Transport Rule or Cross-State Air Pollution Rule (76 FR 48208, Aug.8, 2011).

to the 2006 $PM_{2.5}$ NAAQS, the 1997 $PM_{2.5}$ NAAQS, and the 1997 8-hour ozone NAAQS (76 FR 48208, Aug. 8, 2011). CSAPR was intended to replace the earlier Clean Air Interstate Rule (CAIR) which was judicially remanded.[16] *See North Carolina* v. *EPA,* 531 F.3d 896 (D.C. Cir. 2008). On August 21, 2012, the U.S. Court of Appeals for the D.C. Circuit issued a decision vacating CSAPR, *see EME Homer City Generation, L.P.* v. *E.P.A.,* 696 F.3d 7 (D.C. Cir. 2012), and ordering the EPA to continue implementing CAIR in the interim. However, on April 29, 2014, the U.S. Supreme Court reversed and remanded the D.C. Circuit's ruling and upheld EPA's approach in CSAPR. *EPA* v. *EME Homer City Generation, L.P.,* 134 S. Ct. 1584 (U.S. 2014).

South Dakota's 2006 $PM_{2.5}$ transport analysis contains the State's assessment of the potential for emissions of $PM_{2.5}$ and $PM_{2.5}$ precursors from South Dakota sources to significantly contribute to nonattainment or interfere with maintenance of the 24-hour $PM_{2.5}$ standards in any other state. The State considered distance, population data in South Dakota and other states, and transport modeling conducted for the CAIR in its analysis. The State's analysis and all related documents can be found in the electronic docket for this action.

To determine whether the CAA section 110(a)(2)(D)(i)(I) requirement is satisfied, EPA first determines whether a state's emissions contribute significantly to nonattainment or interfere with maintenance in downwind areas. If a state is determined not to have such contribution or interference, then section 110(a)(2)(D)(i)(I) does not require any changes to a SIP. EPA is proposing to determine that the existing SIP for South Dakota is adequate to satisfy the requirements of 110(a)(2)(D)(i)(I) of the CAA to address interstate transport requirements with regard to the 2006 $PM_{2.5}$ NAAQS. This proposed conclusion is based on air quality modeling originally conducted by EPA during the rulemaking process for CSAPR. This modeling quantified, for each individual state within the modeling domain (including South Dakota), contributions to downwind nonattainment and maintenance areas.

In the CSAPR rulemaking (proposal and final) process, EPA explained how nonattainment and maintenance ''receptors'' would be identified so that contribution to nonattainment and interference with maintenance could be assessed with respect to those receptors.[17] The receptors were identified as all monitoring sites that had $PM_{2.5}$ design values above the level of the 2006 24-hour $PM_{2.5}$ NAAQS (35 $\mu g/m^3$) for certain analytic years. Then EPA compiled an emissions inventory for the year 2005, the most recent year for which EPA had a complete national inventory at that time. In the CSAPR analysis, EPA also projected the inventory for a future year analysis for evaluating the interstate transport impacts in that future year.[18] The air quality modeling, conducted for CSAPR, then evaluated interstate contributions from emissions in upwind states to downwind nonattainment and maintenance receptors for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS. See, Air Quality Modeling Final Rule Technical Support Document, June 2011 (''Air Quality Modeling TSD'') for the CSAPR. Appendix D of the TSD details South Dakota's contribution data for the 2006 24-hour $PM_{2.5}$ NAAQS for all downwind receptors.

EPA then used air quality thresholds to identify linkages between upwind states and downwind nonattainment and maintenance receptors. As detailed in EPA's Air Quality Modeling TSD, EPA used a threshold of 1% of the NAAQS to identify these linkages. Our analysis for CSAPR found that the 1% threshold captures a high percentage of the total pollution transport affecting downwind states for $PM_{2.5}$.[19] The air quality thresholds were therefore calculated as 1% of the NAAQS, which is 0.35 $\mu g/m^3$ for the 2006 24-hour $PM_{2.5}$ NAAQS. EPA found states projected to exceed this air quality threshold at one or more downwind nonattainment receptors emissions to be linked to all such receptors, and therefore subject to further evaluation. EPA did not conduct further evaluation of emissions from states that were not linked to any downwind receptors.

The methodology and modeling used to analyze the impact of emissions from South Dakota and to identify potential linkages between South Dakota and downwind nonattainment and maintenance receptors with respect to the 1997 and 2006 $PM_{2.5}$ NAAQS is described in further detail in the Air Quality Modeling TSD, which is available in the docket for this action.

In its submittal, South Dakota considered factors we have generally found to be relevant for assessing interstate transport for western states that were not within the modeling domain for CSAPR.[20] However, South Dakota was within the modeling domain for CSAPR. As we consider the modeling conducted during the development of CSAPR to contain the most accurate and comprehensive technical assessment of $PM_{2.5}$ interstate transport for those states within its modeling domain, including South Dakota, we examined that analysis to assess transport of $PM_{2.5}$ emissions from South Dakota to other states.

The air quality modeling performed during the development of CSAPR found that the impact from South Dakota emissions on both downwind nonattainment and maintenance receptors was less than the 1% threshold for the 2006 $PM_{2.5}$ NAAQS. Therefore, EPA did not find emissions from South Dakota linked to any downwind nonattainment or maintenance receptors for the 2006 24-hour $PM_{2.5}$ NAAQS.

Below is a summary of the air quality modeling results for South Dakota from Table IV–9 of EPA's Air Quality Modeling TSD regarding South Dakota's largest contribution to both downwind $PM_{2.5}$ nonattainment and maintenance areas.

[15] *See* NO_X SIP Call (63 FR 57371, Oct. 27, 1998); Clean Air Interstate Rule (CAIR) (70 FR 25172, May 12, 2005); and Transport Rule or Cross-State Air Pollution Rule (76 FR 48208, Aug.8, 2011).

[16] CAIR addressed the 1997 annual and 24-hour $PM_{2.5}$ NAAQS, and the 1997 8-hour ozone NAAQS. It did not address the 2006 24-hour $PM_{2.5}$ NAAQS. For more information on CAIR, see the July 30, 2012 proposal for Arizona regarding interstate transport for the 2006 $PM_{2.5}$ NAAQS (77 FR 44551, 44552). In addition, South Dakota was not covered by either CAIR or CSAPR.

[17] For our definition of both nonattainment and maintenance receptors, see the Technical Support Documents for the final CSAPR, including the ''Technical Support Document (TSD) for the Transport Rule—Air Quality Modeling,'' (the proposal TSD) June 2010, and the ''Air Quality Modeling Final Rule Technical Support Document,'' (Air Quality Modeling TSD) June 2011, in the docket for this action.

[18] Emissions Inventory Final Rule TSD, June 28, 2011.

[20] *See* Memorandum from William T. Harnett entitled ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 2006 24-Hour Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS),'' September 25, 2009, available at *http://www.epa.gov/ttn/caaa/t1/memoranda/20090925_harnett_pm25_sip_110a12.pdf.*

TABLE 1—SOUTH DAKOTA'S LARGEST CONTRIBUTION TO DOWNWIND $PM_{2.5}$ NONATTAINMENT AND MAINTENANCE AREAS

NAAQS	Air quality threshold (μg/m3)	Largest downwind contribution to nonattainment (μg/m 3)	Largest downwind contribution to maintenance (μg/m 3)
2006 24-hour $PM_{2.5}$ NAAQS (35 μg/m 3)	0.35	0.10	0.17

Based on this analysis, we propose to approve South Dakota's submission certifying that its SIP meets the requirements of section 110(a)(2)(D)(i)(I) for the 2006 $PM_{2.5}$ NAAQS.

2008 Pb NAAQS

South Dakota's analysis of potential interstate transport for the 2008 Pb NAAQS includes considerations of Pb emissions, the distance of Pb sources in South Dakota to nearby states, and the lack of Pb nonattainment areas near the State's border. The State's analysis is available in the docket for this action.

As noted in our October 14, 2011 Pb Infrastructure Guidance, there is a sharp decrease in Pb concentrations, at least in the coarse fraction, as the distance from a Pb source increases. For this reason, EPA found that the ''requirements of subsection (2)(D)(i)(I) (prongs 1 and 2) could be satisfied through a state's assessment as to whether or not emissions from Pb sources located in close proximity to their state borders have emissions that impact the neighboring state such that they contribute significantly to nonattainment or interfere with maintenance in that state.'' [21] In that guidance document, EPA further specified that any source appeared unlikely to contribute significantly to nonattainment unless it was located less than 2 miles from a state border and emitted at least 0.5 tons per year of Pb. South Dakota's 110(a)(2)(D)(i)(I) analysis specifically noted that there are no sources in the State that meet both of these criteria. EPA concurs with the State's analysis and conclusion that no South Dakota sources have the combination of Pb emission levels and proximity to nearby nonattainment or maintenance areas to contribute significantly to nonattainment in or interfere with maintenance by other states for this NAAQS. South Dakota's SIP is therefore adequate to ensure that such impacts do not occur. We are proposing to approve South Dakota's submission in that its SIP meets the requirements of section 110(a)(2)(D)(i) for the 2008 Pb NAAQS.

2010 NO_2 NAAQS

South Dakota's 2010 NO_2 transport analysis includes considerations of the low level of NO_2 emissions in the State, and specifically notes that the State's main source of NO_2 emissions is in the process of installing pollution control equipment that will decrease its NO_2 emissions by 76%.[22] South Dakota also notes that there are no designated nonattainment areas for the 2010 NO_2 NAAQS, and that the only area that might be considered (according to South Dakota) as a potential maintenance area in the U.S. is hundreds of miles from South Dakota, and in the opposite direction of that in which prevailing winds travel (*i.e.,* west to east) in the western U.S. The State's analysis is available in the docket for this action.

EPA concurs with the technical components of South Dakota's 2010 NO_2 transport analysis. In addition to the factors considered in the State's analysis, EPA also notes that the highest monitored NO_2 design values in each state bordering South Dakota are significantly below the NAAQS (see Table 2, below).[23] This fact further supports the State's contention that significant contribution to nonattainment or interference with maintenance of the NO_2 NAAQS from South Dakota is very unlikely based on the lack of relatively nearby areas with high NO_2.

TABLE 2—HIGHEST MONITORED 2010 NO_2 NAAQS DESIGN VALUES

State	2010–2012 Design value	Percent of NAAQS (100 ppb)
Iowa	42 ppb	42%.
Minnesota	46 ppb	46%.
Montana	42 ppb	42%.
North Dakota	39 ppb	39%.
Nebraska	No Data	No Data.
Wyoming	46 ppb	46%.

* Source: *http://www.epa.gov/airtrends/values.html*

In addition to the monitored levels of NO_2 in states bordering South Dakota being well below the NAAQS, South Dakota's highest design value from 2011–2013 was also significantly below this NAAQS (37 ppb).[24]

Based on all of these factors, EPA concurs with the State's conclusion that South Dakota does not contribute significantly to nonattainment or interfere with maintenance of the 2010 NO_2 NAAQS in other states. EPA is therefore proposing to determine that South Dakota's SIP includes adequate provisions to prohibit sources or other emission activities within the State from emitting NO_2 in amounts that will contribute significantly to nonattainment in or interfere with maintenance by any other state with respect specifically to the NO_2 NAAQS.

[21] ''Guidance on Infrastructure State Implementation Plan (SIP) Elements Required Under Sections 110(a)(1) and 110(a)(2) for the 2008 Lead (Pb) National Ambient Air Quality Standards (NAAQS).'' Steve Page, OAQPS Director, October 14, 2011, at pg 8.

[22] Pollution control equipment is being installed at the Otter Tail Power Company—Big Stone 1, as BART in accordance with regional haze requirements. *See* 77 FR 24845, April 26, 2012.

[23] EPA did not calculate a 2010 one-hour NO_2 design value in the state of Nebraska for the 2010–2012 design value period.

[24] *http://www.epa.gov/airtrends/values.html.*

b. Prongs 3 (PSD) and 4 (Visibility)

South Dakota's certifications with regard to prongs 3 and 4 of element (D) vary by pollutant. Each certification can be found in the docket for this action.

With regard to the PSD portion of section 110(a)(2)(D)(i)(II), this requirement may be met by a state's confirmation in an infrastructure SIP submission that new major sources and major modifications in the state are subject to a SIP-approved PSD program that satisfactorily implements the associated NAAQS. As discussed in more detail with respect to section 110(a)(2)(C), finalization of our proposed approval of certain PSD-related revisions in this action will ensure that South Dakota's SIP-approved PSD program meets current requirements for the 2006 $PM_{2.5}$, 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS. Accordingly, in this action EPA is proposing to approve the infrastructure SIP submission as meeting the applicable requirements of prong 3 of section 110(a)(2)(D)(i) for the 2006 $PM_{2.5}$, 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS.

With regard to the visibility portion of section 110(a)(2)(D)(i)(II), this requirement may be satisfied by a state's regional haze SIP having been approved by EPA as meeting all current obligations. South Dakota submitted a regional haze SIP to EPA on January 21, 2011, and submitted an amendment to the SIP on September 19, 2011. EPA approved South Dakota's Regional Haze SIP on April 26, 2012 (77 FR 24845).

The EPA is proposing to find that as a result of the prior approval of the South Dakota regional haze SIP, the South Dakota SIP contains adequate provisions to address 110(a)(2)(D)(i)(II) visibility requirements with respect to the 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS. Therefore, we are proposing to approve the South Dakota SIP as meeting the requirements of CAA section 110(a)(2)(D)(i)(II) as it applies to visibility for the 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

5. Interstate and International transport provisions: CAA section 110(a)(2)(D)(ii) requires SIPs to include provisions ensuring compliance with the applicable requirements of CAA sections 126 and 115 (relating to interstate and international pollution abatement). Specifically, CAA section 126(a) requires new or modified major sources to notify neighboring states of potential impacts from the source.

Section 126(a) requires notification to affected, nearby states of major proposed new (or modified) sources. Sections 126(b) and (c) pertain to petitions by affected states to the Administrator regarding sources violating the ''interstate transport'' provisions of section 110(a)(2)(D)(i). Section 115 similarly pertains to international transport of air pollution. South Dakota's SIP-approved PSD program incorporates by reference the federal PSD program at 40 CFR 52.21. However, South Dakota separately implements public notice requirements by incorporating by reference (with certain modifications) 40 CFR 51.166(q). In particular, section 51.166(q)(2)(iv), which requires notice to states whose lands may be affected by the emissions of sources subject to PSD, satisfies the notice requirement of section 126(a).

South Dakota has no pending obligations under sections 126(c) or 115(b). Accordingly, South Dakota's SIP currently meets the requirements of those sections. The SIP therefore meets the requirements of 110(a)(2)(D)(ii) for the 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

6. Adequate resources: Section 110(a)(2)(E)(i) requires states to provide necessary assurances that the state will have adequate personnel, funding, and authority under state law to carry out the SIP (and is not prohibited by any provision of federal or state law from carrying out the SIP or portion thereof). Section 110(a)(2)(E)(ii) also requires each state to comply with the requirements respecting state boards under CAA section 128. Section 110(a)(2)(E)(iii) requires states to ''provide necessary assurances that, where the State has relied on a local or regional government, agency, or instrumentality for the implementation of any [SIP] provision, the State has responsibility for ensuring adequate implementation of such [SIP] provision.''

a. Sub-Elements (i) and (iii): Adequate Personnel, Funding, and Legal Authority Under State Law To Carry Out Its SIP, and Related Issues

SDCL 34A–1–57 through 34A–1–60 provide adequate authority for the State of South Dakota and the DENR to carry out its SIP obligations with respect to the 1997 and 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS. The State receives sections 103 and 105 grant funds through its Performance Partnership Grant from EPA along with required state matching funds to provide funding necessary to carry out South Dakota's SIP requirements. South Dakota's resources meet the requirements of CAA section 110(a)(2)(E). The regulations cited by South Dakota in their certifications and contained within this docket also provide the necessary assurances that the State has responsibility for adequate implementation of SIP provisions by local governments. Therefore, we propose to approve South Dakota's SIP as meeting the requirements of section 110(a)(2)(E)(i) and (E)(iii) for the 1997 and 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

b. Sub-Element (ii): State Boards

Section 110(a)(2)(E)(ii) requires each state's SIP to contain provisions that comply with the requirements of section 128 of the CAA. That provision contains two explicit requirements: (i) That any board or body which approves permits or enforcement orders under the CAA shall have at least a majority of members who represent the public interest and do not derive a significant portion of their income from persons subject to such permits and enforcement orders; and (ii) that any potential conflicts of interest by members of such board or body or the head of an executive agency with similar powers be adequately disclosed.

On June 16, 2014, EPA received a submission from the State of South Dakota to address the requirements of section 128. The submission revises language already in the EPA approved SIP at ARSD 74:09, Procedures Board of Minerals and Environment, to address conflict of interest requirements in section 128(a)(2) and adds language in SDCL 1–40–25.1 to address board composition requirements in section 128(a)(1). We propose to approve that June 16, 2014 submission as meeting the requirements of section 128 for the reasons explained in more detail below. Because this revision will meet the requirements of section 128, we also propose to approve the State's infrastructure SIP submissions for element 110(a)(2)(E)(ii). The State made these infrastructure SIP submissions in connection with the 1997 and 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS, but section 128 is not NAAQS-specific and once the State has met the requirements of section 128 that is sufficient for purposes of infrastructure SIP requirements for all of these NAAQS.

We are proposing to approve the State's June 16, 2014 SIP submission as meeting the requirements of section 128 because we believe that it complies with the statutory requirements and is consistent with EPA's guidance recommendations concerning section 128. In 1978, EPA issued a guidance memorandum recommending ways states could meet the requirements of section 128, including suggested interpretations of certain key terms in

section 128.[25] In this proposal notice, we discuss additional relevant aspects of section 128. We first note that, in the conference report on the 1977 amendments to the CAA, the conference committee stated, ''[i]t is the responsibility of each state to determine the specific requirements to meet the general requirements of [section 128].'' [26] This legislative history indicates that Congress intended states to have some latitude in adopting SIP provisions with respect to section 128, so long as states meet the statutory requirements of the section. We also note that Congress explicitly provided in section 128 that states could elect to adopt more stringent requirements, as long as the minimum requirements of section 128 are met.

In implementing section 128, the EPA has identified a number of key considerations relevant to evaluation of a SIP submission. EPA has identified these considerations in the 1978 guidance and in subsequent rulemaking actions on SIP submissions relevant to section 128, whether as SIP revisions for this specific purpose or as an element of broader actions on infrastructure SIP submissions for one or more NAAQS.

Each state must meet the requirements of section 128 through provisions that EPA approves into the state's SIP and are thus made federally enforceable. Section 128 explicitly mandates that each SIP ''shall contain requirements'' that satisfy subsections 128(a)(1) and 128(a)(2). A mere narrative description of state statutes or rules, or of a state's current or past practice in constituting a board or body and in disclosing potential conflicts of interest, is not a requirement contained in the SIP and does not satisfy the plain text of section 128.

Subsection 128(a)(1) applies only to states that have a board or body that is composed of multiple individuals and that, among its duties, approves permits or enforcement orders under the CAA. It does not apply in states that have no such multi-member board or body that performs these functions, and where instead a single head of an agency or other similar official approves permits or enforcement orders under the CAA. This flows from the text of section 128, for two reasons. First, as subsection 128(a)(1) refers to a majority of members of the board or body in the plural, we think it reasonable to read subsection 128(a)(1) as not creating any requirements for an individual with sole authority for approving permits or enforcement orders under the CAA. Second, subsection 128(a)(2) explicitly applies to the head of an executive agency with ''similar powers'' to a board or body that approves permits or enforcement orders under the CAA, while subsection 128(a)(1) omits any reference to heads of executive agencies. We infer that subsection 128(a)(1) should not apply to heads of executive agencies who approve permits or enforcement orders.

Subsection 128(a)(2) applies to all states, regardless of whether the state has a multi-member board or body that approves permits or enforcement orders under the CAA. Although the title of section 128 is ''State boards,'' the language of subsection 128(a)(2) explicitly applies where the head of an executive agency, rather than a board or body, approves permits or enforcement orders. In instances where the head of an executive agency delegates his or her power to approve permits or enforcement orders, or where statutory authority to approve permits or enforcement orders is nominally vested in another state official, the requirement to adequately disclose potential conflicts of interest still applies. In other words, EPA interprets section 128(a)(2) to apply to all states, regardless of whether a state board or body approves permits or enforcement orders under the CAA or whether a head of a state agency (or his/her delegees) performs these duties. Thus, all state SIPs must contain provisions that require adequate disclosure of potential conflicts of interest in order to meet the requirements of subsection 128(a)(2). The question of which entities or parties must be subject to such disclosure requirements must be evaluated by states and EPA in light of the specific facts and circumstances of each state's regulatory structure.

A state may satisfy the requirements of section 128 by submitting for adoption into the SIP a provision of state law that closely tracks or mirrors the language of the applicable provisions of section 128. A state may take this approach in two ways. First, the state may adopt the language of subsections 128(a)(1) and 128(a)(2) verbatim. Under this approach, the state will be able to meet the continuing requirements of section 128 without any additional, future SIP revisions, even if the state adds or removes authority, either at the state level or local level, to individual or to boards or bodies to approve permits or enforcement orders under the CAA so long as the state continues to meet section 128 requirements. Second, the state may modify the language of subsections 128(a)(1) (if applicable) and 128(a)(2) to name the particular board, body, or individual official with approval authority. In this case, if the state subsequently modifies that authority, the state may have to submit a corresponding SIP revision to meet the continuing requirements of section 128. If the state chooses to not mirror the language of section 128, the state may adopt state statutes and/or regulations that functionally impose the same requirements as those of section 128, including definitions for key terms such as those recommended in EPA's 1978 guidance. While any of these approaches would meet the minimum requirements of section 128, the statute also explicitly authorizes states to adopt more stringent requirements, for example to impose additional requirements for recusal of board members from decisions, above and beyond the explicit board composition requirements. Although such recusal alone does not meet the requirements of section 128, states have the authority to require that over and above the explicit requirements of section 128. These approaches give states flexibility in implementing section 128, while still ensuring consistency with the statute.

EPA has evaluated the June 16, 2014 submission from the State in light of the requirements of section 128 and these key considerations. South Dakota state law establishes a nine-member Board of Minerals and Environment (BME) (SDCL 1–40–25). Under state law, air permits and enforcement orders that are issued by the Secretary can be appealed to the BME in a contested case hearing (SDCL 34A–1–21 (permits), 34A–1–46, 34A–1–48 (orders)). In addition, the BME has authority to hold contested case hearings on air permits on its own initiative (SDCL 34A–1–21), and has certain direct enforcement authorities (SDCL 34A–1–40, 34A–1–44). As EPA has explained in other rulemaking actions, *e.g.,* 78 FR 32613 (May 31, 2013), we interpret section 128(a)(1) to mean that boards that are the potential final decisionmaker via permit and enforcement order appeals ''approve'' those permits and enforcement orders. For example, by being the final decisionmaker with respect to questions such as whether a source receives a permit and the specific contents of such a permit, the board is an entity that approves the permit within the meaning of 128(a)(1). Thus, the BME is subject to the requirements of 128(a)(1). South Dakota's June 16, 2014 submission

[25] Memorandum from David O. Bickart, Deputy General Counsel, to Regional Air Directors, Guidance to States for Meeting Conflict of Interest Requirements of Section 128 (Mar. 2, 1978).

[26] H.R. Rep. 95–564 (1977), reprinted in 3 *Legislative History of the Clean Air Act Amendments of 1977,* 526–27 (1978).

includes a statute, SDCL 1–40–25.1, which provides that the BME must be composed in conformance with requirements of section 128 of the CAA for all permits and enforcement orders initiated under South Dakota's air pollution control authority. Thus, the State has submitted a legally binding requirement for inclusion into the SIP that requires the BME to be comprised of a majority of members that represent the public interest and do not receive a substantial portion of their income from parties subject to permit requirements or enforcement orders under the CAA. We propose to approve this submission as satisfying the requirements of subsection 128(a)(1).

To meet the requirements of subsection 128(a)(2), the State's June 16, 2014 submittal includes disclosure requirements applying to members of the BME. Members of the BME must disclose ''potential conflicts of interest'' as defined in ARSD 74:09:01:21 in a contested case proceeding on the record at the initiation of the hearing, or during the hearing if they become aware of the existence of a potential conflict of interest. In addition, members with a ''conflict of interest'' as defined in ARSD 74:09:01:20 must make a statement of recusal on the record at the initiation of the hearing and may not participate in board discussions or decision-making regarding that proceeding. Conflicts of interest are broadly defined in ARSD 74:09:01:20 as any ''board member who is personally related to a party involved in a contested case hearing by two degrees of consanguinity, who has direct financial interest in a party involved in a contested case hearing through employment or by contract, or whose spouse is employed by or directly contracts with a party involved in a contested case hearing.'' Furthermore, a potential conflict of interest is defined in ARSD 74:09:01:21 as ''an indirect financial interest, or a personal relationship or another interest in a party involved in a contested case hearing or enforcement hearing that is different from that of the general public, that a reasonable person would believe might result in bias or prejudgment of a contested case hearing.'' EPA thinks these definitions of ''conflict of interest'' and ''potential conflict of interest,'' taken in tandem, are sufficiently broad to address the types of conflicts of interest that should be disclosed under 128(a)(2). While not precisely consistent with the types of conflicts addressed in our 1978 guidance for section 128, in some ways South Dakota's provisions are in fact broader. In addition, we think that disclosure on the record at the start of a hearing is an adequate form of disclosure. Such disclosure will provide public access to the relevant information about conflicts of interest and memorialize that information.

EPA's review of the State's June 16, 2014 submission has raised one issue that warrants further evaluation. Section 128(a)(2) requires that a state's SIP provide for adequate disclosure of conflicts of interest by ''members of such board or body or the head of an executive agency with similar powers.'' The use of the disjunctive ''or'' between ''board or body'' and ''head of an executive agency'' results in ambiguity concerning whether merely one or both of these parties must disclose conflicts of interest, and if it is only one of these entities, which one? This ambiguity is relevant in the case of the submission from the State because under state law included within such submission, only the members of the BME are required to disclose conflicts of interest, not the head of the executive agency. In order to determine whether this is sufficient for purposes of meeting the requirements of section 128(a)(2), we have evaluated the statutory language more closely.

First, the term ''or'' can be interpreted as ''one or the other, but not necessarily both,'' or it can be interpreted as ''and.'' Although the word ''or'' could be read to mean ''and'' in some circumstances, we believe that in this instance it is appropriate to give the word ''or'' its most straightforward meaning. In isolation, it could seem unreasonable to give ''or'' the first meaning, as that would allow a state to require adequate disclosure of conflict of interest by either the members of the state board or the head of an agency, without regard to whether that disclosure requirement applies to the entity that makes the final permit or enforcement order decision. To read section 128(a)(2) to require disclosure by the entity that is not the actual final decisionmaker appears logically inconsistent and contrary to the overall purposes of section 128. EPA believes that the purpose of section 128(a)(2) is to assure that conflicts of interest are disclosed by the entity making the permit or enforcement order decision, and requiring this of the ultimate decisionmaker rather than other parties that may be involved in the process.

As discussed above, under South Dakota law all members of the BME have to disclose conflicts of interest in specified ways that we believe are adequate. Under the structure of the State's program, the Secretary makes certain decisions such as the issuance of air permits and enforcement orders. However, under state law these permits and enforcement orders issued by the Secretary can be appealed to the BME in a contested case hearing (SDCL 34A–1–21 (permits), 34A–1–46, 34A–1–48 (orders)). In addition, the BME has authority to hold contested case hearings on air permits on its own initiative (SDCL 34A–1–21), and has certain direct enforcement authorities (SDCL 34A–1–40, 34A–1–44). Given this division of authority in the State, we believe that the BME is functionally the final decisionmaker with respect to permits and enforcement orders in South Dakota, and thus the disclosure of conflicts of interest by members of the BME is necessary to meet the requirements of section 128(a)(2). Naturally, a state may elect to require disclosure of conflicts of interest by other state officials and employees as well, and this would be fully consistent with the explicit reservation of authority for states to impose more stringent requirements than those imposed by section 128.

For the foregoing reasons, the EPA believes that the June 16, 2014 submission from South Dakota contains provisions that meet the requirements of section 128(a)(1) and section 128(a). Accordingly, we are proposing approval of that submission and also proposing approval of the infrastructure SIP submission as meeting the requirements of section 128.

7. Stationary source monitoring system: Section 110(a)(2)(F) requires: (i) The installation, maintenance, and replacement of equipment, and the implementation of other necessary steps, by owners or operators of stationary sources to monitor emissions from such sources, (ii) Periodic reports on the nature and amounts of emissions and emissions-related data from such sources, and (iii) Correlation of such reports by the state agency with any emission limitations or standards established pursuant to the Act, which reports shall be available at reasonable times for public inspection.

The South Dakota statutory provisions listed in the State's certifications (SDCL 34A–1–6 and SDCL 34A–1–12) and contained within this docket provide authority to establish a program for measurement and testing of sources, including requirements for sampling and testing. South Dakota's SIP approved continuous emissions monitoring system rules (ARSD 74:36:13 and contained within this docket) require facilities to monitor and report emission data. ARSD 74:36:04:15(10), contents of operating permit, requires operating permits for minor sources to

include monitoring and related record keeping and reporting requirements. Reports contain the quantity of hazardous air pollutants, in tons, emitted for each 12-month period in the reporting period and supporting documentation. Operating permits for minor sources must comply with emission limits and other requirements of the Act (ARSD 74:36:04:04 and ARSD 74:36:04:15). Additionally, ARSD 74:36:05:16.01(9) is applicable regarding data from sources with title V permits. South Dakota has an approved title V program (61 FR 2720, Jan. 29, 1996) and the definition of applicable requirements for a Part 70 source has been approved into its SIP at ARSD 74:36:01:05. This re-enforces a facility's record keeping and reporting emissions data responsibilities under title V permitting, even though the title V program is not approved into the SIP.

Additionally, South Dakota is required to submit emissions data to the EPA for purposes of the National Emissions Inventory (NEI). The NEI is the EPA's central repository for air emissions data. The EPA published the Air Emissions Reporting Rule (AERR) on December 5, 2008, which modified the requirements for collecting and reporting air emissions data (73 FR 76539). The AERR shortened the time states had to report emissions data from 17 to 12 months, giving states one calendar year to submit emissions data. All states are required to submit a comprehensive emissions inventory every three years and report emissions for certain larger sources annually through the EPA's online Emissions Inventory System. States report emissions data for the six criteria pollutants and their associated precursors—nitrogen oxides, sulfur dioxide, ammonia, lead, carbon monoxide, particulate matter, and volatile organic compounds. Many states also voluntarily report emissions of hazardous air pollutants. South Dakota made its latest update to the NEI on January 9, 2014. EPA compiles the emissions data, supplementing it where necessary, and releases it to the general public through the Web site *http://www.epa.gov/ttn/chief/eiinformation.html*.

Based on the analysis above, we propose to approve the South Dakota SIP as meeting the requirements of CAA section 110(a)(2)(F) for the 1997 and 2006 $p.m._{2.5,}$ 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

8. Emergency powers: Section 110(a)(2)(G) of the CAA requires infrastructure SIPs to ''provide for authority comparable to that in [CAA section 303] and adequate contingency plans to implement such authority.'' Section 303 reads as follows:

> Notwithstanding any other provision of this chapter, the Administrator, upon receipt of evidence that a pollution source or combination of sources (including moving sources) is presenting an imminent and substantial endangerment to public health or welfare, or the environment, may bring suit on behalf of the United States in the appropriate United States district court to immediately restrain any person causing or contributing to the alleged pollution to stop the emission of air pollutants causing or contributing to such pollution or to take such other action as may be necessary. If it is not practicable to assure prompt protection of public health or welfare or the environment by commencement of such a civil action, the Administrator may issue such orders as may be necessary to protect public health or welfare or the environment. Prior to taking any action under this section, the Administrator shall consult with appropriate State and local authorities and attempt to confirm the accuracy of the information on which the action proposed to be taken is based. Any order issued by the Administrator under this section shall be effective upon issuance and shall remain in effect for a period of not more than 60 days, unless the Administrator brings an action pursuant to the first sentence of this section before the expiration of that period. Whenever the Administrator brings such an action within the 60-day period, such order shall remain in effect for an additional 14 days or for such longer period as may be authorized by the court in which such action is brought.

Thus, the EPA Administrator has authority to bring suit to immediately restrain an air pollution source that presents an imminent and substantial endangerment to public health or welfare, or the environment. If such action may not practicably assure prompt protection, then the Administrator has authority to issue temporary administrative orders to protect the public health or welfare, or the environment, and such orders can be extended if EPA subsequently files a civil suit. The 1990 Amendments to the Act modified Section 303.[27]

EPA's 2013 Infrastructure SIP Guidance (for the 2008 ozone, 2010 NO_2, 2010 sulfur dioxide, and all future NAAQS), represents EPA's most recent guidance, which we've cited earlier in this notice given its broad applicability, states that the best practice for states is to submit, for inclusion in the SIP, the statutory or regulatory provisions that provide authority comparable to CAA section 303 or to cite and include a copy of such provisions, without including them in the SIP, with a narrative of how they meet the requirements of section 110(a)(2)(G).[28]

We propose to find that South Dakota's Infrastructure SIP Submittals and certain State statutes provide for authority for the State comparable to that granted to the EPA Administrator to act in the face of an imminent and substantial endangerment to public's health or welfare, or the environment.

South Dakota's SIP submittals with regard to the section 110(a)(2)(G) emergency order requirements explain that:

> SDCL section 34A–1–45 (Emergency order for immediate reduction or discontinuance of emissions) is comparable to Section 303 of the Clean Air Act and provides that ''*if the Secretary of the Department of Environment and Natural Resources finds that any person is causing or contributing to air pollution and that such pollution creates an emergency by*

[27] Section 303 of CAA as modified in 1990 substituted the term ''public health or welfare, or the environment'' for ''the health of persons,'' eliminated the requirement for state or local inaction as a prerequisite to EPA initiating action, and lengthened the duration of administrative orders from 24 hours to 60 days. The Senate Report on the 1990 Amendments explained that:

> These amendments to section 303 of the Act, as well as parallel (sic) amendments to section 113, have several purposes. The (sic) amendments broaden the Administrator's (sic) authority to issue emergency orders to abate threats to welfare and the environment, in addition to the authority to respond to threats to ''the health of persons.'' In addition, the amendments eliminate the 24- to 48-hour time limit on the effectiveness of emergency orders. These changes are necessary to enable the Administrator to address air pollution emergencies in an adequate manner, and to conform the Administrator's emergency authority under the Act to emergency authorities under other environmental laws. See, TSCA section 208, CERCLA section 106, RCRA section 7003, and CWA section 504. Similarly, the deletion of the requirement that the Administrator may not bring suit unless State or local authorities have failed to act conforms the Act to other environmental laws.
>
> Broadening section 301 to include harm to the environment is important to enable EPA to address emergency threats to ecosystems in instances where there is no readily demonstrable immediate threat to human health. For example, toxic emissions might be blowing downwind from a facility into an undeveloped natural area and threatening to impair that area's ecosystem. This amendment will allow EPA to order the plant to take necessary steps to eliminate the threat to flora and fauna. Deleting the unrealistically short time limits on the duration of orders is necessary to ensure that these orders are a viable enforcement tool. In order to protect State interests and to prevent duplication of effort, this section requires that the Administrator consult with the State and local authorities before taking any action. The enforcement provision, section 303(b), has been deleted as unnecessary because emergency orders have been made enforceable under section 113.
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> S. Rep. No. 101–228, 101 Cong., 1st Sess. 370. EPA's 1999 guidance on section 303 contains additional information regarding the legislative history of this section. While the guidance indicates it ''is intended to be used by EPA as internal guidance only and does not establish any substantive or procedural rights'' we include the guidance in the proposed docket for this action as background information. ''Transmittal Memo and Guidance Document on Section 303 of the Clean Air Act,'' Eric. V. Schaeffer, Director, Office of Regulatory Enforcement, EPA Office of Enforcement and Compliance Assurance (April 1, 1999).

[28] 2013 Infrastructure SIP Guidance, pp. 47–50.

causing imminent danger to human health or safety and requires immediate action to protect human health or safety, the Secretary shall order such person or persons to reduce or discontinue immediately the emission of air contaminants.'' [29]

Accordingly, we have reviewed South Dakota's statutory provisions for evidence that the State has authorities comparable to those in section 303. Our review included the provision discussed above, as well as provisions in the current SDCL.[30] None of these state laws have been submitted for incorporation into the South Dakota SIP.

With regard to the authority to bring suit, SDCL 34A–10–1 extends the right to the ''attorney general, any political subdivision of the state, any instrumentality or agency of the state or of a political subdivision thereof, any person partnership, limited liability company, corporation, association, organization, or other legal entity'' to ''maintain an action'' for ''declaratory and equitable relief . . . against any person . . . for the protection of the air, water, and other natural resources and the public trust therein from pollution, impairment, or destruction.'' In addition, SDCL 34A–10–2 states that ''[i]f administrative, licensing, or other proceedings, and judicial review thereof are available by law, the agency may permit the attorney general, any political subdivision of the state, any instrumentality or agency of the state or of a political subdivision thereof, any person, partnership, limited liability company, corporation, association, organization, or other legal entity to intervene'' in that proceeding involving ''conduct which has the effect of polluting, impairing, or destroying the air, water, or other natural resources or the public thrust therein.'' SDCL 21–10–1 through 21–10–9 also provide the State with the authority regarding nuisances, including the authority to seek specific remedies against nuisances (SDCL 21–10–5). The definitions of acts and omissions constituting nuisances provide the State with broad authority to bring suit against persons causing pollution and injury or endangering the health or safety of others (SDCL 21–10–1).

By using terms such as ''pollution, impairment, or destruction,'' and ''protection of the air, water, and other natural resources,'' these statutes (SDCL 34A–10–1, 34A–10–2) provide stated entities with broad authority to bring suit against persons causing pollution of varying degrees of urgency, including pollution that presents an imminent and substantial endangerment.[31] These provisions provide arguably broader authority than what CAA section 303 provides to EPA, as they do not by their terms first require the stated entities to assert that the would-be enjoined pollution constitutes imminent and substantial endangerment. We propose to find that these provisions, while not specifically mentioning ''public health,'' ''welfare,'' or the ''environment,'' are nonetheless comparable to section 303 and broadly empower the State to address through civil action threats to public health (*e.g.,* from pollution), welfare (*e.g.,* from nuisances, and for protection of the air, water, and other natural resources), and the environment (*e.g.,* protection of natural resources from pollution, impairment, or destruction) from any imminent and substantial endangerment.

South Dakota's statutes also provide DENR's Secretary with the authority to issue administrative orders and emergency rules, and suspend state agency rules, to protect the public health, welfare, and the environment under certain circumstances. SDCL 34A–1–45, as cited in South Dakota's SIP submittals, authorizes that if the Secretary of the DENR ''finds that any person is causing or contributing to air pollution and that such pollution creates an emergency by causing imminent danger to human health or safety and requires immediate action to protect human health or safety,'' ''the secretary shall order the person to reduce or discontinue immediately the emission of air contaminants.'' The emergency order is effective immediately on service upon the person responsible for the emission, and any person to whom such an order is directed shall comply with the order immediately. SDCL 34A–10–2.5 provides authority for the DENR to apply to the court for an injunction, including temporary injunctions, against any person who fails to comply with such orders.

Additionally, SDCL 1–26–5(3) authorizes any agency to adopt or amend an emergency rule for reasons including ''imminent peril to the public health, safety, or welfare . . . or because of the occurrence of an unforeseen event at a time when the adoption of a rule in response to such event by the emergency procedure is required to secure or protect the best interests of the state or its residents.'' Subject to applicable constitutional or statutory provisions, emergency rules are ''effective immediately upon filing with the secretary of state'' or at another stated date; and ''[n]o emergency rule may remain in effect for a period of no longer than ninety days'' (SDCL 1–26–8). South Dakota's statutes also require that certain procedures be followed prior to adoption of the emergency rule. ''[A]n agency shall publish a notice of intent to adopt an emergency rule in the manner prescribed in section 1–26–4.1'' (SDCL 1–26–5). SDCL 1–26–4.1 provides that ''the notice of intent to adopt an emergency rule shall be mailed to each person who has made a timely request of the agency for advance notice of its rule-making proceedings.'' SDCL requires that the agency ''serve on the person specified in subdivision 1–26–4(1),[32] each member of the Interim Rules Committee and the director'' the information specified in SDCL 1–26–5 and follow the notification and mailing requirements in SDCL 1–25–4.1. Finally, SDCL 1–26–5(3) requires that notice of proposed emergency rule served on the specified individuals shall include ''[a] statement, with the reasons, that the emergency procedure is necessary: because of imminent peril to

[29] We note that the South Dakota Legislature's compilation of statutes indicates that SDCL section 34A–1–45 reads slightly differently from the language that appears in the infrastructure SIP submission, and additionally, does not contain the last sentence of the paragraph. This proposed action considers the statute as it appears on the State's compilation, which reads as follows: ''34A–1–45. Emergency order for immediate reduction or discontinuance of emissions. If the secretary finds that any person is causing or contributing to air pollution and that such pollution creates an emergency by causing imminent danger to human health or safety and requires immediate action to protect human health or safety, the secretary shall order the person to reduce or discontinue immediately the emission of air contaminants. The emergency order is effective immediately on service upon the person responsible for the emission, and any person to whom such an order is directed shall comply with the order immediately.'' (Available online at: *http://legis.sd.gov/Statutes/Codified_Laws/DisplayStatute.aspx?Type=Statute&Statute=34A-1-45,* accessed October 8, 2014).

[30] October 29, 2014 conference call with Brian Gustafson, Kyrik Rombough, Steven Blair, and Roxanne Giedd from the State of South Dakota and Carl Daly, Monica Morales, Sara Laumann, and Abby Fulton from EPA Region 8 regarding feedback on EPA's interpretation of South Dakota's authority comparable to section 303. The State indicated they generally agreed with our analysis.

[31] Notably, South Dakota's definition of ''air pollutant,'' which is a term that triggers the authority contained in several of the applicable provisions, contains a threshold injury requirement relating to injury to human health, welfare or the environment. Under South Dakota law, ''air pollutant'' is defined as, ''the presence in the outdoor atmosphere of one or more contaminants in such quantity and duration as is or tend to be injurious to human health or welfare, animals or plant life, or property or would interfere with the enjoyment of life or property.'' SDCL 34A–1–2(2).

[32] SDCL 1–26–4(1) requires that the agency ''shall serve a copy of a proposed rule and any publication described in section 1–26–6.6 upon the departmental secretary, bureau commissioner, public utilities commissioner, or constitutional officer to which it is attached for the secretary's, commissioner's, or officer's written approval to proceed.''

the public health, safety, or welfare; . . . or because of the occurrence of an unforeseen event at a time when the adoption of a rule in response to such event by the emergency procedure is required to secure or protect the best interests of the state or its residents.'' While these provisions do not directly provide authority to issue administrative orders to prevent air pollution that endangers the environment and contain certain notification procedures not found in section 303, they do provide regulatory authority for state agencies to develop emergency rules for the protection of public health and welfare, and welfare is commonly understood to include the elements of what is covered by the term ''environment'' (see, *e.g.*, CAA section 302(h), broadly defining ''effects on welfare'').

We also note that another emergency management option under South Dakota statutes involves the Governor's authorities. For example, Chapter 34–48A, which covers Emergency Management, includes authority for the Governor to issue orders in emergency situations.[33] Additionally, in the event of an ''emergency'' [34] that is beyond local government capability, SDCL 34–48A–5(4) gives the Governor authority to suspend rules under certain circumstances.[35]

While no single South Dakota statute mirrors the authorities of CAA section 303, we propose to find that the combination of SDCL provisions discussed above provide for authority comparable to section 303 to immediately bring suit to restrain, issue emergency executive orders against, and use special rule adoption and suspension procedures for applicable emergencies to take prompt administrative action against, any person causing or contributing to air pollution that presents an imminent and substantial endangerment to public health or welfare, or the environment. Consistent with EPA's 2013 Infrastructure SIP Guidance, the narratives provided in South Dakota's SIP submittals about the State's authorities applying to emergency episodes (as discussed above), plus additional South Dakota statutes that we have considered, we propose that they are sufficient to meet the authority requirement of CAA section 110(a)(2)(G).

States must also have adequate contingency plans adopted into their SIP to implement the air agency's emergency episode authority (as discussed above). This can be met by submitting a plan that meets the applicable requirements of 40 CFR part 51, subpart H for the relevant NAAQS if the NAAQS is covered by those regulations. Rules contained in ARSD and South Dakota's SIP adopt by reference the criteria in 40 CFR 51.151 as the air quality episode plan to address activities causing imminent and substantial endangerment to public health, including a contingency plan to implement the emergency episode provisions of the SIP. As of the date of South Dakota's submittal, EPA has not established priority classification for a significant harm level for $PM_{2.5}$. As DENR explains in its SIP submittals, once EPA promulgates such rules, DENR will adopt them into ARSD 74:36:03 (Air quality episodes).

Subpart H of 40 CFR part 51 requires states to classify regions and to develop contingency plans (also known as emergency episode plans) after ambient concentrations of certain criteria pollutants in an area have exceeded specified levels. For example, if ambient concentrations of nitrogen dioxide in an area have exceeded 0.06 ppm (annual arithmetic mean), then the area is classified as a Priority I region, and the state must develop a contingency plan that meets the requirements of sections 51.151 and 51.152. However, Subpart H does not currently address requirements for the 24-hour $PM_{2.5}$ standard.

In 2009, EPA issued a guidance memorandum that, among other things, recommended an approach for states to address the contingency plan requirements of 110(a)(2)(G) with respect to the 2006 $PM_{2.5}$ NAAQS.[36] The guidance, in Attachment A, suggested that states develop a contingency plan if, based on the most recent three calendar years of data, an area within the state had monitored and recorded a 24-hour $PM_{2.5}$ level greater than 140.4 $\mu g/m^3$. For states that were to develop a contingency plan, the guidance recommended states set priority and emergency levels consistent with requirements of 40 CFR 51.150 through 51.153. EPA notes that section 51.153 requires periodic reevaluation of priority classifications based on the three most recent years of air quality data.

South Dakota has recorded no levels of ambient air concentrations in the three most recent complete calendar years—2011, 2012, and 2013—that exceed the 2009 guidance memorandum [37] recommended levels for states to develop a contingency plan for $PM_{2.5}$. However, on September 4, 2009 a continuous $PM_{2.5}$ air monitor operated by the State of South Dakota in Wind Cave National Park registered a 24-hour level of 303.6 $\mu g/m^3$. The monitor in question was a special purpose Federal Equivalent Method monitor collocated with a Federal Reference Method (FRM) State and Local Air Monitoring Stations (SLAMS) monitor. The SLAMS FRM was designated as the primary monitor at the site, and recorded 120.5 $\mu g/m^3$ as the official regulatory value for the monitoring station that day. On the day the secondary monitor recorded a value of 303.6 $\mu g/m^3$, the National Park Service conducted a prescribed burn in the Wind Cave National Park. A discussion including details of the event as well as monitoring data are contained within a memo to this docket. Given the unique circumstances of this event and taking into account that the official regulatory value fell below the recommended level for developing a contingency plan, and that the last three years of data also fall below the recommended level, EPA believes it is appropriate to interpret 110(a)(2)(G) as not requiring development of a contingency plan. However, this does not imply that other, future

[33] SDCL 34–48A–9. ''Power to make orders. In performing his duties under this chapter, and to effect its policy and purpose, the Governor is further authorized and empowered to make, amend, and rescind the necessary orders to carry out the provisions of this chapter within the limits of the authority conferred upon him herein, with due consideration of the plans of the federal government.''

[34] SDCL 34–48A–1(3) defines emergency as ''any natural, nuclear, man-made, war- related, or other catastrophe producing phenomena in any part of the state which in the determination of the Governor requires the commitment of less than all available state resources to supplement local efforts of political subdivisions of the state to save lives and to protect property, public health, and safety or to avert or lessen the threat of a disaster.''

[35] SDCL 34–48A–5(4) gives the Governor the authority to ''suspend the provisions of any rules of any state agency if strict compliance with the provisions of the rule would in any way prevent, hinder, or delay necessary action in managing a disaster . . . or emergency, including . . . air contamination . . . which is determined by the Governor to require state or state and federal assistance or actions to supplement the recovery efforts of local government in alleviating the damage, loss, hardship, or suffering caused thereby.'' The rules suspended by the Governor remain suspended for six months and may be restored for one or more successive six-month periods if the Governor declares the conditions persist (SDCL 34–48A–5).

[36] Memorandum from William T. Harnett, Director, Air Quality Policy Division, to Regional Air Division Directors, Guidance on SIP Elements Required under Sections 110(a)(1) and (2) for the 2006 24-Hour Fine Particle ($PM_{2.5}$) Standards (NAAQS), at p. 6–7 (Sep. 25, 2009).

[37] Memorandum from William T. Harnett, Director, Air Quality Policy Division, to Regional Air Division Directors, Guidance on SIP Elements Required under Sections 110(a)(1) and (2) for the 2006 24-Hour Fine Particle ($PM_{2.5}$) Standards (NAAQS), at p. 6–7 (Sep. 25, 2009).

circumstances in the state cannot trigger this requirement.

Revisions to the South Dakota Air Quality Episodes rules ARSD 74:36:03:01 ''Air pollution emergency episode'' and ARSD 74:36:03:02 ''Episode emergency contingency plan'' were most recently approved on June 27, 2014 (79 FR 36425). We find that South Dakota's air pollution emergency rules include $PM_{2.5,}$ ozone, and NO_2; establish stages of episode criteria; provide for public announcement whenever any episode stage has been determined to exist; and specify emission control actions to be taken at each episode stage, consistent with the EPA emergency episode SIP requirements set forth at 40 CFR part 51 subpart H (prevention of air pollution emergency episode) for particulate matter, ozone, and NO_2.

As noted in the October 14, 2011 guidance,[38] based on EPA's experience to date with the Pb NAAQS and designating Pb nonattainment areas, EPA expects that an emergency episode associated with Pb emissions would be unlikely and, if it were to occur, would be the result of a malfunction or other emergency situation at a relatively large source of Pb. Accordingly, EPA believes the central components of a contingency plan would be to reduce emissions from the source at issue and communicate with the public as needed. We note that 40 CFR part 51, subpart H (51.150–51.152) and 40 CFR part 51, Appendix L do not apply to Pb.

Based on the above analysis, we propose approval of South Dakota's SIP as meeting the requirements of CAA section 110(a)(2)(G) for the 1997 and 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

9. Future SIP revisions: Section 110(a)(2)(H) requires that SIPs provide for revision of such plan: (i) From time to time as may be necessary to take account of revisions of such national primary or secondary ambient air quality standard or the availability of improved or more expeditious methods of attaining such standard, and (ii), except as provided in paragraph (3)(C), whenever the Administrator finds on the basis of information available to the Administrator that the SIP is substantially inadequate to attain the NAAQS which it implements or to otherwise comply with any additional requirements under this [Act].

South Dakota's statutory provision at SDCL 34A–1–6 gives DENR sufficient authority to meet the requirements of 110(a)(2)(H). Therefore, we propose to approve South Dakota's SIP as meeting the requirements of CAA section 110(a)(2)(H).

10. Consultation with government officials, public notification, PSD and visibility protection: Section 110(a)(2)(J) requires that each SIP ''meet the applicable requirements of section 121 of this title (relating to consultation), section 127 of this title (relating to public notification), and part C of this subchapter (relating to PSD of air quality and visibility protection).''

The State has demonstrated it has the authority and rules in place through its certifications (contained within this docket) to provide a process of consultation with general purpose local governments, designated organizations of elected officials of local governments and any Federal Land Manager having authority over federal land to which the SIP applies, consistent with the requirements of CAA section 121. Furthermore, EPA previously addressed the requirements of CAA section 127 for the South Dakota SIP and determined public notification requirements are appropriate (45 FR 58528, Sept. 4, 1980).

As discussed above, the State has a SIP-approved PSD program that incorporates by reference the federal program at 40 CFR 52.21. EPA has further evaluated South Dakota's SIP approved PSD program in this proposed action under element (C) and determined the State has satisfied the requirements of element 110(a)(2)(C), as noted above. Therefore, the State has also satisfied the requirements of element 110(a)(2)(J).

Finally, with regard to the applicable requirements for visibility protection, EPA recognizes states are subject to visibility and regional haze program requirements under part C of the Act. In the event of the establishment of a new NAAQS, however, the visibility and regional haze program requirements under part C do not change. Thus, we find that there are no applicable visibility requirements under section 110(a)(2)(J) when a new NAAQS becomes effective.

Based on the above analysis, we propose to approve the South Dakota SIP as meeting the requirements of CAA section 110(a)(2)(J) for the 1997 and 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

11. Air quality and modeling/data: Section 110(a)(2)(K) requires each SIP provide for: (i) The performance of such air quality modeling as the Administrator may prescribe for the purpose of predicting the effect on ambient air quality of any emissions of any air pollutant for which the Administrator has established a NAAQS, and (ii) the submission, upon request, of data related to such air quality modeling to the Administrator.

South Dakota's PSD program incorporates by reference the federal program at 40 CFR 52.21, including the provision at 40 CFR 52.21(l)(1) requiring that estimates of ambient air concentrations be based on applicable air quality models specified in Appendix W of 40 CFR part 51, and the provision at 40 CFR 52.21(l)(2) requiring that modification or substitution of a model specified in Appendix W must be approved by the Administrator.

Additionally, SDLC section 34A–1–1, 34A–1–10, and 1–40–31 provide the Department with the authority to advise, consult, and cooperate with EPA and provide EPA with public records, such as air quality modeling. As a result, the SIP provides for such air quality modeling as the Administrator has prescribed. Therefore, we propose to approve the South Dakota SIP as meeting the CAA section 110(a)(2)(K) for the 1997 and 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

12. Permitting fees: Section 110(a)(2)(L) requires SIPs to: Require the owner or operator of each major stationary source to pay to the permitting authority, as a condition of any permit required under this act, a fee sufficient to cover; (i) the reasonable costs of reviewing and acting upon any application for such a permit; and (ii) if the owner or operator receives a permit for such source, the reasonable costs of implementing and enforcing the terms and conditions of any such permit (not including any court costs or other costs associated with any enforcement action), until such fee requirement is superseded with respect to such sources by the Administrator's approval of a fee program under title V.

The funding sources used for the PSD permit reviews conducted by South Dakota derive from EPA grant and matching State general funds.[39] There are no nonattainment areas in the State. In light of the State's experience that funding from grants and general funds has been sufficient to operate a successful PSD program, it is reasonable that the PSD permit applicants are not charged any permit-specific fees.

We also note that all the State SIPs we are proposing to approve in this action

[38] ''Guidance on Infrastructure State Implementation Plan (SIP) Elements Required Under Sections 110(a)(1) and 110(a)(2) for the 2008 Lead (Pb) National Ambient Air Quality Standards (NAAQS).'' Steve Page, OAQPS Director, October 14, 2011, at p 13.

[39] *See* Email from Brian Gustafson ''Question Regarding Permitting Fees for SD iSIP Action'' July 24, 2014, available within docket.

cite the regulation that provides for collection of permitting fees under the State's EPA-approved title V permit program (ARSD 74:37:01), which we approved and became effective February 28, 1996 (61 FR 2720, Jan. 29, 1996).

Therefore, based on the State's experience in relying on the grant and general funds for PSD permits, and the use of title V fees to implement and enforce PSD permits once they are incorporated into title V permits, we propose to approve the submissions as supplemented by the State for the 1997 and 2006 p.m.$_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

13. Consultation/participation by affected local entities: Section 110(a)(2)(M) requires states to provide for consultation and participation in SIP development by local political subdivisions affected by the SIP.

The statutory provisions cited in South Dakota's SIP submittals (contained within this docket) meet the requirements of CAA section 110(a)(2)(M), so we propose to approve South Dakota's SIP as meeting these requirements for the 1997 and 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

VII. What action is EPA taking?

In this action, EPA is proposing to approve the following infrastructure elements for the 1997 and 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS: (A), (B), (C) with respect to minor NSR and PSD requirements, (D)(i)(II) prongs 3 and 4, (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M). EPA is also proposing to approve revisions to ARSD 74:36:09 submitted on July 29, 2013, which incorporate by reference the requirements of the 2010 $PM_{2.5}$ Increment Rule. Specifically, we propose to approve the adoption of the text of 40 CFR 52.21, paragraphs (b)(14)(i),(ii),(iii), (b)(15)(i),(ii), and paragraph (c) as they existed on July 1, 2012 by proposing to approve revisions to: ARSD 74:34:09:02 (Prevention of significant deterioration) and 74:36:09:03 (Public participation). EPA is also proposing to approve revisions to ARSD 74:09 and SDCL 1–40–25.1 submitted on June 11, 2014 to satisfy requirements of element (E)(ii), state boards. Finally, EPA proposes approval of D(i)(I) prongs 1 and 2 for the 2006 $PM_{2.5}$, 2008 Pb, and 2010 NO_2 NAAQS. EPA will act separately on infrastructure element (D)(i)(I), interstate transport for the 2008 ozone NAAQS.

VIII. Statutory and Executive Orders Review

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations (42 U.S.C. 7410(k), 40 CFR 52.02(a)). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves some state law as meeting federal requirements and disapproves other state law because it does not meet federal requirements; this proposed action does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, Oct. 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, Aug. 10, 1999); is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and,
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, Feb. 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, Nov. 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Greenhouse gases, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: November 19, 2014.

Shaun L. McGrath,

Regional Administrator, Region 8.

[FR Doc. 2014–28301 Filed 11–28–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2012–0353; FRL–9919–96–Region 8]

Approval and Promulgation of Air Quality Implementation Plans; State of Montana Second 10-Year Carbon Monoxide Maintenance Plan for Great Falls

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing approval of a State Implementation Plan (SIP) revision submitted by the State of Montana. On July 13, 2011, the Governor of Montana's designee submitted to EPA a second 10-year maintenance plan for the Great Falls area for the carbon monoxide (CO) National Ambient Air Quality Standard (NAAQS). This maintenance plan addresses maintenance of the CO NAAQS for a second 10-year period beyond the original redesignation. EPA is also proposing approval of an alternative monitoring strategy for the Great Falls CO maintenance area, which was submitted by the Governor's designee on June 22, 2012.

DATES: Comments must be received on or before December 31, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2012–0353, by one of the following methods:

- *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Email: clark.adam@epa.gov.*
- *Fax:* (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).

• *Mail:* Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129.

• *Hand Delivery:* Director, Air Program, EPA, Region 8, Mail Code 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129. Such deliveries are only accepted Monday through Friday, 8:00 a.m. to 4:30 p.m., excluding federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R08–OAR–2012–0353. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA, without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to Section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly-available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air Program, EPA, Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Adam Clark, Air Program, EPA, Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129, (303) 312–7104, *clark.adam@epa.gov.*

SUPPLEMENTARY INFORMATION:

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The initials *ADT* mean or refer to Average Daily Traffic.

(iii) The initials *CO* mean or refer to carbon monoxide.

(iv) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(v) The initials *LMP* mean or refer to Limited Maintenance Plan.

(vi) The initials *MDEQ* mean or refer to Montana Department of Environmental Quality.

(vii) The initials *MVEB* mean or refer to Motor Vehicle Emissions Budget.

(viii) The initials *NAAQS* mean or refer to the National Ambient Air Quality Standards.

(ix) The initials *ppm* mean or refer to parts per million.

(x) The initials *RTP* mean or refer to Regional Transportation Plan.

(xi) The initials *SIP* mean or refer to State Implementation Plan.

(xii) The initials *TIP* mean or refer to Transportation Improvement Plan.

(xiii) The words *Montana* and *State* mean or refer to the State of Montana.

I. General Information

What should I consider as I prepare my comments for EPA?

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

2. *Tips for preparing your comments.* When submitting comments, remember to:

• Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register**, date, and page number);

• Follow directions and organize your comments;

• Explain why you agree or disagree;

• Suggest alternatives and substitute language for your requested changes;

• Describe any assumptions and provide any technical information and/or data that you used;

• If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced;

• Provide specific examples to illustrate your concerns and suggest alternatives;

• Explain your views as clearly as possible, avoiding the use of profanity or personal threats; and

• Make sure to submit your comments by the comment period deadline identified.

II. Background

A. Great Falls CO Maintenance Plan

Under the Clean Air Act (CAA) Amendments of 1990, the Great Falls area was designated as nonattainment and classified as a ''not classified'' CO area. This was because the area had been designated as nonattainment before November 15, 1990, but had not violated the CO NAAQS in 1988 and 1989 (56 FR 56694, November 6, 1991). On February 9, 2001, the Governor of Montana submitted to us a request to redesignate the Great Falls CO nonattainment area to attainment for the CO NAAQS. Along with this request, the Governor submitted a CAA section 175A(a) maintenance plan which demonstrated that the area would maintain the CO NAAQS for the first 10 years following our approval of the redesignation request. We approved the State's redesignation request and 10-year maintenance plan on May 9, 2002 (67 FR 31143).

Eight years after an area is redesignated to attainment, CAA section 175A(b) requires the state to submit a subsequent maintenance plan to EPA,

covering a second 10-year period.[1] This second 10-year maintenance plan must demonstrate continued compliance with the NAAQS during this second 10-year period. To fulfill this requirement of the CAA, the Governor of Montana's designee submitted the second 10-year update of the Great Falls CO maintenance plan (hereafter; ''revised Great Falls Maintenance Plan'') to us on July 13, 2011. With this action, we are proposing approval of the revised Great Falls Maintenance Plan.

The 8-hour CO NAAQS—9.0 parts per million (ppm)—is attained when such value is not exceeded more than once a year. 40 CFR 50.8(a)(1). The Great Falls area has attained the 8-hour CO NAAQS from 1988 to the present. In October 1995, EPA issued guidance that provided nonclassifiable CO nonattainment areas the option of using a less rigorous ''limited maintenance plan'' (LMP) option to demonstrate continued attainment and maintenance of the CO NAAQS.[2] According to this guidance, areas that can demonstrate design values (2nd highest max) at or below 7.65 ppm (85% of exceedance levels of the 8-hour CO NAAQS) for eight consecutive quarters qualify to use an LMP. The area qualified for and used EPA's LMP option for the first 10-year Great Falls CO maintenance plan (67 FR 31143, May 9, 2002). For the revised Great Falls Maintenance Plan the State again used the LMP option to demonstrate continued maintenance of the CO NAAQS in the Great Falls area. We have determined that the Great Falls area continues to qualify for the LMP option because the maximum design value for the most recent eight consecutive quarters with certified data at the time the State adopted the plan (years 2008 and 2009) was 1.6 ppm.[3]

B. Alternative CO Monitoring Strategy

Along with the revised Great Falls Maintenance Plan, the State submitted a CO maintenance plan for the Billings, Montana maintenance area, and an alternative strategy for monitoring continued attainment of the CO NAAQS in all of the State's CO maintenance areas on July 13, 2011.[4] The State submitted the alternative monitoring strategy to conserve resources by discontinuing the gaseous CO ambient monitors in both the Billings and Great Falls CO maintenance areas. In place of the gaseous ambient monitors, the State's alternative method relies on rolling 3-year Average Daily Traffic (ADT) vehicle counts collected from permanent automatic traffic recorders in each maintenance area. We commented on the State's ''Alternative Monitoring Strategy,'' and the State submitted to us a revised version of the strategy which incorporated our comments on June 22, 2012. The State's June 22, 2012 Alternative Monitoring Strategy replaced the version submitted on July 13, 2011.

III. EPA's Evaluation of Montana's Alternative Monitoring Strategy in Great Falls

Since 2002, no Great Falls CO monitor has registered a design value greater than 2.8 ppm, which is below one-third of the NAAQS.[5] Citing these consistently low monitor values, and expressing a desire to conserve monitoring resources, the State has requested to discontinue CO monitoring in Great Falls and instead use an alternative strategy for monitoring maintenance of the CO NAAQS.

The State's Alternative Monitoring Strategy utilizes ADT vehicle counts collected from permanent automatic traffic recorders in the Great Falls CO maintenance area to determine average monthly traffic during the traditional high CO concentration season of November through February. The State will compare the latest rolling 3-years of monthly ADT volumes to the 2008–2010 baseline ADT volumes (see Table 1) that correlate to the low CO monitored values during that period (see Table 2). Because mobile sources are the biggest driver of CO pollution, the Montana Department of Environmental Quality (MDEQ) reasoned that any significant increase in CO emissions would have to be accompanied by a significant increase in ADT.[6] EPA agrees with the State's reasoning.

TABLE 1—TRAFFIC VOLUMES FOR GREAT FALLS, MONTANA

[Rolling 2008–2010 ADT: November to February]

Month-Year	Great Falls (#A–033)
January 2008	34,123
February 2008	36,855
November 2008	35,675
December 2008	33,584
January 2009	33,820
February 2009	36,102
November 2009	37,110
December 2009	34,742
January 2010	34,371
February 2010	36,576
November 2010	34,164
December 2010	34,691
Average	35,151

TABLE 2—8-HOUR CO DESIGN VALUES FOR GREAT FALLS, MONTANA

Design value (ppm)[7]	Year
2.8	2002
2.7	2003
2.4	2004
2	2005
1.7	2006
1.5	2007
1.5	2008
1.6	2009
1.9	2010
0.9	2011

If the rolling 3-year ADT value is 25% higher than the average value of 35,151 from the 2008–2010 baseline period, the State will reestablish CO ambient monitoring in Great Falls the following high season (November–February). If the CO design value in that season has not increased from the baseline mean by an equal or greater rate at which ADT has increased, and the monitor values remain at or below 50% of the CO NAAQS (2nd max concentration ≤4.5 ppm), the monitor may again be removed and the ADT counts will continue to be relied upon to determine compliance with the NAAQS. This process will be repeated each time the rolling 3-year ADT increases by a factor of 25% (*e.g.* 50%, 75%) above the baseline 2008–2010 period, and the same analysis will be conducted to determine if the monitors can again be removed.

40 CFR 58.14(c) allows approval of requests to discontinue ambient monitors ''on a case-by-case basis if discontinuance does not compromise data collection needed for implementation of a NAAQS and if the requirements of appendix D to 40 CFR

[1] In this case, the initial maintenance period extended through 2012. Thus, the second 10-year period extends through 2022.

[2] Memorandum ''Limited Maintenance Plan Option for Nonclassifiable CO Nonattainment Areas'' from Joseph W. Paisie, Group Leader, EPA Integrated Policy and Strategies Group, to Air Branch Chiefs, October 6, 1995.

[3] See Table 2 below. Additionally, according to the LMP guidance, an area using the LMP option must continue to have a design value ''at or below 7.65 ppm until the time of final EPA action on the redesignation.'' Table 2, below, demonstrates that the area meets this requirement.

[4] In addition to Great Falls and Billings, the Missoula, MT CO maintenance area was included in the July 13, 2011 Alternative Monitoring Strategy.

[5] See Table 2 below. Design values were derived from the EPA AirData (*http://www.epa.gov/airdata/*) Web site.

[6] See ''Review of National Ambient Air Quality Standards for Carbon Monoxide,'' 76 FR 54294, August 31, 2011.

[7] Design values were derived from the EPA AirData (*http://www.epa.gov/airdata/*) Web site.

part 58, if any, continue to be met.'' EPA finds that the Alternative Monitoring Strategy meets the criteria of 40 CFR 58.14(c) for the Great Falls CO maintenance area. Given the long history of low CO concentrations in the Great Falls area, and the adequacy of the Alternative Monitoring Strategy at ensuring continued attainment of the CO NAAQS, EPA finds it appropriate to approve the State's request to discontinue the Great Falls monitor and use the Alternative Monitoring Strategy in its place.

IV. EPA's Evaluation of the Great Falls Second 10-Year CO Maintenance Plan

The following are the key elements of an LMP for CO: Emission Inventory, Maintenance Demonstration, Monitoring Network/Verification of Continued Attainment, Contingency Plan, and Conformity Determinations. Below, we describe our evaluation of each of these elements as it pertains to the revised Great Falls Maintenance Plan.

A. Emission Inventory

The revised Great Falls Maintenance Plan contains an emissions inventory for the base year 2009. The emission inventory is a list, by source, of the air contaminants directly emitted into the Great Falls CO maintenance area on a typical winter day in 2009.[8] The mobile sources data in the emission inventory in the July 13, 2011 submittal were developed using emissions modeling methods that EPA did not consider up-to-date. After consultation with EPA, the State then provided EPA with technical information to clarify and supplement the emissions inventory from the July 13, 2011 submittal.[9] This supplemental technical information utilized EPA-recommended mobile sources emissions modeling methods (MOVES2010b).[10] The Great Falls LMP and supplementary technical information contain detailed emission inventory information that was prepared in accordance with EPA guidance and is acceptable to EPA.[11]

B. Maintenance Demonstration

We consider the maintenance demonstration requirement to be satisfied for areas that qualify for and use the LMP option. As mentioned above, a maintenance area is qualified to use the LMP option if that area's maximum 8-hour CO design value for eight consecutive quarters does not exceed 7.65 ppm (85% of the CO NAAQS). EPA maintains that if an area begins the maintenance period with a design value no greater than 7.65 ppm, the applicability of prevention of significant deterioration requirements, the control measures already in the SIP, and federal measures should provide adequate assurance of maintenance over the 10-year maintenance period. Therefore, EPA does not require areas using the LMP option to project emissions over the maintenance period. Because CO design values in the Great Falls area are consistently well below the LMP threshold (See Table 2), the State has adequately demonstrated that the Great Falls area will maintain the CO NAAQS into the future.

C. Monitoring Network/Verification of Continued Attainment

In the revised Great Falls Maintenance Plan, the State commits to ''continue to monitor CO using an instrumental method or a functionally equivalent monitoring methodology as approved by EPA.'' As noted, EPA is proposing to approve the State's Alternative Monitoring Strategy for the Great Falls CO maintenance area as part of this action. Based on final approval of the Alternative Monitoring Strategy, we will have concluded that the strategy is adequate to verify continued attainment of the CO NAAQS in Great Falls.

D. Contingency Plan

Section 175A(d) of the CAA requires that a maintenance plan include contingency provisions to promptly correct any violation of the NAAQS that occurs after redesignation of an area. To meet this requirement, the State has identified appropriate contingency measures along with a schedule for the development and implementation of such measures.

The Great Falls Maintenance Plan stated in section 7.10.6.4 that the State will use an exceedance of the CO NAAQS as the trigger for adopting specific contingency measures for the Great Falls area. As noted, the Alternative Monitoring Strategy requires reinstitution of a CO monitor in Great Falls if traffic levels increase from the 2008–2010 baseline by a factor of 25%. Therefore, EPA finds that CO emissions in Great Falls are very unlikely to increase to the point of an exceedance without that exceedance being observed by a gaseous monitor.

The State indicates that notification of an exceedance to EPA and to the local governments in the Great Falls area will occur within 60 days. Upon notification of a CO NAAQS exceedance, MDEQ and Cascade City/County Health Department (CCCHD) will recommend an appropriate contingency measure or measures that would be necessary to avoid a violation of the CO NAAQS standard. The necessary contingency measure(s) will then be proposed for local adoption. Finalization of the necessary contingency measures for local adoption will be completed within three months of the exceedance notification. Full implementation of the locally adopted contingency measure(s) will be achieved within one year after the recording of a CO NAAQS violation.

The potential contingency measures, identified in section 7.10.6.4.C of the Great Falls Maintenance Plan, include implementation of a mandatory oxygenated fuels program with local regulations in the Great Falls or Cascade County area for the winter months of November, December, and January, and establishing an episodic woodburning curtailment program. A more complete description of the triggering mechanism and these contingency measures can be found in section 7.10.6.4 of the Great Falls Maintenance Plan.

We find that the contingency measures provided in the State's maintenance plan for Great Falls are sufficient and meet the requirements of section 175A(d) of the CAA.

E. Transportation Conformity

Transportation conformity is required by section 176(c) of the CAA. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS (CAA 176(c)(B)). EPA's conformity rule provisions in 40 CFR part 93, Subpart A require that transportation plans, programs and projects conform to SIPs and establish the criteria and procedures for determining whether or not they demonstrate conformity. EPA's conformity rule provisions include requirements for a demonstration that emissions from the Regional Transportation Plan (RTP) and the Transportation Improvement Program (TIP) are consistent with the motor vehicle emission budget (MVEB) contained in the SIP revision (40 CFR 93.118 and 93.124). The MVEB is defined as the level of mobile source emissions relied upon in the attainment or maintenance demonstration to maintain compliance with the NAAQS

[8] Violations of the CO NAAQS are most likely to occur on winter weekdays.

[9] The supplemental technical information was sent to EPA on July 23, 2014, and is available in the docket for this action.

[10] Motor Vehicle Emissions Simulator (MOVES) model; version 2010b.

[11] ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' from John Calcagni, September 4, 1992.

in the nonattainment or maintenance area.[12]

Under the LMP policy, emissions budgets are treated as essentially not constraining for the length of the maintenance period. While EPA's LMP policy does not exempt an area from the need to affirm conformity, it explains that the area may demonstrate conformity without submitting a MVEB. This is because it is unreasonable to expect that an LMP area will experience so much growth in that period that a violation of the CO NAAQS would result.[13] Therefore, for the Great Falls CO maintenance area, all actions that require conformity determinations for CO under our conformity rule provisions are considered to have already satisfied the regional emissions analysis and ''budget test'' requirements in 40 CFR 93.118.

Since LMP areas are still maintenance areas, certain aspects of transportation conformity determinations are still required for transportation plans, programs and projects. Specifically, for such determinations, RTPs, TIPs and projects must still demonstrate that they are fiscally constrained (40 CFR 93.108) and must meet the criteria for consultation and Transportation Control Measure implementation in the conformity rule provisions (40 CFR 93.112 and 40 CFR 93.113, respectively). In addition, projects in LMP areas will still be required to meet the applicable criteria for CO hot spot analyses to satisfy ''project level'' conformity determinations (40 CFR 93.116 and 40 CFR 93.123) which must also incorporate the latest planning assumptions and models available (40 CFR 93.110 and 40 CFR 93.111 respectively).

In view of the CO LMP policy, the effect of this proposed approval will be to affirm our adequacy finding such that no regional emissions analyses for future transportation CO conformity determinations are required for the CO LMP period and beyond (as per EPA's CO LMP policy and 40 CFR 93.109(e)).

V. Proposed Action

EPA is proposing to approve the revised Great Falls Maintenance Plan submitted on July 13, 2011. This maintenance plan meets the applicable CAA requirements and EPA has determined it is sufficient to provide for maintenance of the CO NAAQS over the course of the second 10-year maintenance period out to 2022.

EPA is also proposing to approve the State's Alternative Monitoring Strategy for the Great Falls CO maintenance area. We do not propose to approve application of the Alternative Monitoring Strategy in other areas of Montana with this action, as the Alternative Monitoring Strategy must be considered on a case-by-case basis specific to the circumstances of each particular CO maintenance area rather than broadly.

VI. Statutory and Executive Orders Review

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

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

Dated: November 10, 2014.

Shaun L. McGrath,

Regional Administrator, Region 8.

[FR Doc. 2014–28293 Filed 11–28–14; 8:45 am]

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[12] EPA's transportation conformity requirements and policy on MVEBs are found in the preamble to the November 24, 1993, transportation conformity rule (see 58 FR 62193–62196) and in the sections of 40 CFR part 93 referenced above.

[13] Limited Maintenance Plan Guidance at 4. October 6, 1995.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2013–0786; A–1–FRL–9918–26–Region–1]

Approval and Promulgation of Air Quality Implementation Plans; Massachusetts; Transit System Improvements

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Massachusetts on November 6, 2013. This proposal, if finalized, would remove the design of the Red Line/Blue Line Connector as a requirement in the Massachusetts SIP, without substitution or replacement, and would implement administrative changes that lengthen the existing public process by fifteen days and replace references to the Executive Office of Transportation (EOT) with references to the Massachusetts Department of Transportation (MassDOT). This action is being taken under the Clean Air Act.

DATES: Written comments must be received on or before December 31, 2014.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R01–OAR–2013–0786 by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: arnold.anne@epa.gov.*
3. *Fax:* (617) 918–0047.
4. *Mail:* ''Docket Identification Number EPA–R01–OAR–2013–0786,'' Anne Arnold, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912.
5. *Hand Delivery or Courier:* Deliver your comments to: Anne Arnold, Manager, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, (mail code OEP05–2), Boston, MA 02109–3912. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R01–OAR–2013–0786. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *www.regulations.gov,* or email, information that you consider to be CBI or otherwise protected. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

In addition, copies of the state submittal are also available for public inspection during normal business hours, by appointment at the State Air Agency; Air and Climate Division, Department of Environmental Protection, One Winter Street, 8th Floor, Boston, MA 02108.

FOR FURTHER INFORMATION CONTACT: Donald O. Cooke, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912, telephone number (617) 918–1668, fax number (617) 918–0668, email *cooke.donald@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

Organization of this document. The following outline is provided to aid in locating information in this preamble.

I. Background
II. Massachusetts' 2013 SIP Revision Submittal
A. Deletion of the Design of the Red Line/Blue Line Connector
B. Administrative Changes
III. Proposed Action
IV. Statutory and Executive Order Reviews

I. Background

On December 9, 1991, the Massachusetts Department of Environmental Protection (MassDEP) submitted a revision to its SIP for Transit System Improvements and HOV (High Occupancy Vehicle) Lanes in the Metropolitan Boston Air Pollution Control District. This SIP revision committed the Massachusetts Executive Office of Transportation and Construction (MA EOTC) to pursue implementation, monitoring, and enforcement of transit system improvements and HOV lanes that were identified as transportation and air quality mitigation measures in a 1990 Final Supplemental Environmental Impact Statement for the Central Artery/Third Harbor Tunnel (CA/THT) project. EPA determined five of the proposed transportation control measures (TCMs) were necessary to help achieve an air quality benefit from the CA/THT. This 1991 SIP revision included the following two new regulations: 310 Code of Massachusetts Regulations (CMR) 7.36, ''Transit System Improvements;'' and 310 CMR 7.37, ''High Occupancy Vehicle Lanes.''

This initial transit system improvement and high occupancy vehicle lanes SIP revision was approved by EPA on October 4, 1994 (59 FR 50495) and required the Transit System Improvement Projects in Table 1 to be completed and available for public use by the dates specified below:

TABLE 1—COMMITMENT TO TRANSIT SYSTEM IMPROVEMENT PROJECTS IN 310 CMR 7.36

[State effective date December 6, 1991]

Projects must be completed and available for public use by:	Transit system improvement projects
December 31, 1992	—Lynn Central Square Station and Parking Garage, —North Station high platforms and high tracks, —Lynn Transit Station Bus Terminal.
December 31, 1994	—South Station Bus Terminal,

TABLE 1—COMMITMENT TO TRANSIT SYSTEM IMPROVEMENT PROJECTS IN 310 CMR 7.36—Continued

[State effective date December 6, 1991]

Projects must be completed and available for public use by:	Transit system improvement projects
December 31, 1996	—South Station Track Number 12, —Ipswich Commuter Rail Line extension to Newburyport. —Old Colony Commuter Rail Line Extension, —Framingham Commuter Rail Line Extension to Worcester, —10,000 Park and Ride and Commuter Rail parking spaces outside of the Boston core.
December 31, 1997	—Green Line Arborway Restoration.
December 31, 1998	—Blue Line platform lengthening and modernization.
December 31, 1999	—10,000 Park and Ride and Commuter Rail Station Parking spaces outside of the Boston core in addition to those completed by December 31, 1996.
December 31, 2001	—South Boston Piers Electric Bus Service.
December 31, 2011	—Green Line extension to Ball Square/Tufts University, —Blue Line Connection from Bowdoin Station to the Red Line at Charles Station.

On December 13, 2006, the MassDEP submitted a revision to its SIP amending its Transit System Improvements Regulation. The revision consisted of MassDEP's final amendments to 310 CMR 7.36, ''Transit System Improvements,'' with a state effective date of December 1, 2006. In the revised rule, three of the SIP-required projects, the Green Line Arborway Restoration, the Blue Line Connection from Bowdoin Station to the Red Line at Charles Station, and the Green Line extension to Ball Square/Tufts University, were replaced by the Fairmount Line commuter rail improvements project (construction to be completed and opened to full public use by December 31, 2011), 1,000 new park and ride parking spaces serving Massachusetts Bay Transportation Authority (MBTA) transit and commuter rail in the Metropolitan Boston Area (construction to be completed and opened to full public use by December 31, 2011), final design of the connection from the Blue Line at Government Center to the Red Line at Charles Station (final design before December 31, 2011, but no commitment to its construction), and an enhanced Green Line transit extension to Medford Hillside with a spur to Union Square (construction to be completed and opened to full public use by December 31, 2014).

On June 1, 2007, MassDEP supplemented its December 13, 2006 SIP revision with Massachusetts Executive Office of Transportation's (EOT's) amended air quality modeling analysis report (''Description of Modeling Assumptions and Analysis Methodology for the State Implementation Plan Transit Commitment Projects Current and Proposed Substitutions,'' dated March 15, 2007) and a letter determining that EOT had met the requirements of 310 CMR 7.36(8), Determination of Air Quality Emissions Reductions, including a determination that the Fairmount Line improvements, 1,000 new park-and-ride parking spaces, and the Green Line extension to Medford Hillside with a spur to Union Square would achieve at least 110% of the emissions reductions that would have been achieved had the Arborway Restoration, Red Line/Blue Line Connector, and Green Line extension to Ball Square been constructed. EOT held a public comment period on the modeling analysis report for a 45-day period commencing on January 2, 2007. EOT then amended the report based on comments received and commenced an additional two-week public comment period on March 21, 2007, following posting in the Massachusetts' ''Environmental Monitor.'' MassDEP also submitted EOT's responses to public comments received as part of the supplemental materials.

On November 5, 2007 (72 FR 62422), EPA published a Notice of Proposed Rulemaking for the Commonwealth of Massachusetts' December 13, 2006 SIP revision as amended by the June 1, 2007 supplement. [See EPA Docket number EPA–R01–OAR–2006–1018 at *www.regulations.gov*]. In evaluating the proposed replacement/substitution transit projects for the Green Line Arborway Restoration, the Red Line/Blue Line Connector, and the Green Line extension to Ball Square/Tufts University (see Table 2), EPA ensured that the substitution provisions in 310 CMR 7.36(5), Substitute Transit System Improvement Projects, which were adopted into the Massachusetts SIP, were satisfied and followed the ''Interim Guidance for Implementing the Transportation Conformity Provisions in the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU),'' (EPA420–B–06–901, February 2006). As Massachusetts' TCM substitution mechanisms were approved into the SIP prior to SAFETEA–LU's enactment, Massachusetts must continue to use its SIP-approved TCM substitution mechanisms in addition to the new SAFETEA–LU statutory provision, as applicable, to make substitutions.

TABLE 2—REPLACEMENT TRANSIT SYSTEM IMPROVEMENT PROJECTS IN 310 CMR 7.36

[State effective date December 1, 2006]

Projects must be completed and available for public use by:	Transit system improvement projects to replace the Green Line Arborway Restoration, the Blue Line Connection from Bowdoin Station to the Red Line at Charles Station, and the Green Line extension to Ball Square/Tufts University:
December 31, 2011	—Fairmont Line commuter rail improvements project.
December 31, 2011	—1000 new park and ride parking spaces serving MBTA transit and commuter rail in the Metropolitan Boston Area.
December 31, 2011	—Final design of the connection from the Blue Line at Government Center to the Red Line at Charles Station. [Final design but no commitment to its construction].
December 31, 2014	—Enhanced Green Line transit extension to Medford Hillside with a spur to Union Square.

On July 31, 2008 (73 FR 44654), EPA approved Massachusetts' amendments to Transit System Improvements Regulation, 310 CMR 7.36, and Definitions Regulation, 310 CMR 7.00 (with a state effective date of December 1, 2006), as a revision to the Massachusetts SIP. This revision changed completion dates of delayed transit projects, provided interim deadlines for projects, maintained requirements for interim emission reduction offsets in the event a project becomes delayed, modified the project substitution process, revised the list of required transit projects, and expanded public participation in, and oversight of, the projects. The intended effect of this action was to substitute specific transit projects and 1,000 park and ride spaces to replace certain transit projects previously approved into the SIP and to approve modifications to the delay and substitution procedures for transit projects.

EPA found that the transit measures in the December 1, 2006 Revised Transit System Improvements Regulation remained directionally sound and that all substitution projects identified in the Regulation would collectively contribute to achieving the national ambient air quality standard for ozone and maintaining the carbon monoxide standard, thereby satisfying requirements set forth in section 110(l) of the Clean Air Act.

II. Massachusetts' 2013 SIP Revision Submittal

Massachusetts Air Pollution Control regulation 310 CMR 7.36, ''Transit System Improvements'' (effective December 1, 2006), is currently incorporated-by-reference into the SIP. The Commonwealth's November 6, 2013 SIP submittal requests that EPA approve the replacement of this regulation in the SIP by an amended 310 CMR 7.36, ''Transit System Improvements'' (effective October 25, 2013). The amended regulation: (1) Deletes the SIP requirement to design the Red Line/Blue Line Connector from the Blue Line at Government Center to the Red Line at Charles Station; (2) lengthens by fifteen days the time within which MassDEP must hold a public meeting to take public comment on MassDOT's annual update and status report; and (3) replaces references to Executive Office of Transportation and EOT with Massachusetts Department of Transportation and MassDOT, respectively. These three amendments are addressed in more detail below.

EPA's role in this proposed action is to approve state choices, provided they meet the criteria of the Clean Air Act. An adequate SIP revision is one that meets the Clean Air Act requirement under section 110(l) that a SIP revision must not interfere with attainment and maintenance of national ambient air quality standards (NAAQS) or any other applicable requirement of the Act. The Commonwealth has flexibility to revise SIP-approved TCMs, provided the revisions are consistent with attaining and maintaining compliance with the NAAQS.

A. Deletion of the Design of the Red Line/Blue Line Connector

The first amendment deletes the requirement that MassDOT complete the final design of the Red Line/Blue Line Connector from the Blue Line at Government Center to the Red Line at Charles Station by December 31, 2011. Although 310 CMR 7.36(2)(i), as adopted in 2006, required MassDOT to complete the final design of the Red Line/Blue Line Connector, the regulation did not require that the project be constructed. MassDOT took a number of steps to advance the Red Line/Blue Line Connector design, including, but not limited to, allocating resources to advance the conceptual design, completing a Draft Environmental Impact Report, and forming and meeting with a working group. MassDOT has estimated that $50 million would be needed to complete the final design, far exceeding the $29 million last identified in the Boston Metropolitan Planning Organization (MPO) 2009 Regional Transportation Plan (RTP). MassDOT has determined that allocating additional and scarce transportation funding to the final design of the project is not justified. Therefore, in July 2011, MassDOT requested that MassDEP remove the Red Line/Blue Line Connector design from the regulation and the SIP.

SAFETEA–LU, which was signed into law on August 10, 2005, revised a number of aspects of the Clean Air Act's section 176(c) transportation conformity provisions. In addition to amendments to the transportation conformity provisions, SAFETEA–LU also added a provision to section 176(c) to allow states to substitute or add TCMs into approved SIPs without the standard SIP revision process. This allowed a streamlined process for substituting and adding TCMs to an approved SIP. Where a substitution is not proposed, however, a TCM may only be removed from an applicable SIP through a standard SIP revision. Such a SIP revision must be shown to meet Clean Air Act section 110(l) requirements (*e.g.,* the area would have to show that removal of the TCM would not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable Clean Air Act requirement).

Since the Massachusetts SIP revision is for the removal of a SIP requirement without replacement or substitution, EPA believes the provisions of 310 CMR 7.36(5), Substitute Transit System Improvement Projects, and EPA's Guidance for Implementing the Clean Air Act Section 176(c)(8) Transportation Control Measure Substitution and Addition Provision do not apply.[1] Most importantly, as the previously approved SIP requirement is for design only, removing this requirement from the SIP will not affect the total emission reductions achieved from the projects included in the Massachusetts Transit System Improvements Regulation and would not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable Clean Air Act requirement, thereby satisfying the requirements set forth in section 110(l) of the Clean Air Act. Therefore, EPA is proposing to approve this amendment.

B. Administrative Changes

EOT/MassDOT, in consultation with the MBTA, is required to develop and submit to MassDEP by July 1st of each year a report for each project required by the Transit System Improvements Regulation [310 CMR 7.36(2)(f) through (j) and any project implemented pursuant to 310 CMR 7.36(4) and (5)] in accordance with the provisions established at 310 CMR 7.36(7)(a) of the Transit System Improvements Regulation's Public Process Requirements. Following receipt of the report, MassDEP is required to conduct a public meeting to take public comment on EOT/MassDOT's update and status report. Because MassDEP is required to conduct the public meeting within 60 days of its receipt of the report, there have been conflicts with the Labor Day Holiday and the end of summer season. Therefore, in the revised regulation submitted on November 6, 2013, MassDEP lengthened the public meeting deadline to within 75 days of the receipt of the report to avoid these conflicts. The additional fifteen days will still result in a timely hearing on MassDOT's updates and reports, and should enable more stakeholders and members of the public to participate.

MassDEP shall continue to provide public notice at least 30 days prior to

[1] The guidance is available at *http://www.epa.gov/otaq/stateresources/transconf/policy/420b09002.pdf.*

the public meeting and shall also make copies of MassDOT's annual update and status report available to the public at least 30 days prior to the public meeting. EPA finds the fifteen day extension acceptable since it will benefit the public review and comment opportunities and will not affect emissions or interfere with any applicable requirement concerning attainment and reasonable further progress or any other applicable Clean Air Act requirement. Therefore, EPA is proposing to approve this amendment. If our proposal is finalized, MassDEP will hold future public meeting on the annual update and status report within seventy-five days of MassDEP's receipt of the report. *See* 310 CMR 7.36(7)(b).

In addition, in the revised regulation submitted on November 6, 2013, the terms ''Executive Office of Transportation'' and ''EOT'' have been replaced with ''Massachusetts Department of Transportation'' and ''MassDOT,'' respectively, to reflect Chapter 25 of the Acts of 2009. In June 2009, Governor Deval Patrick signed Chapter 25 of the Acts of 2009, ''An Act Modernizing the Transportation Systems of the Commonwealth of Massachusetts,'' (as amended by Chapter 26 of the ''Act''). This transportation reform legislation integrated transportation agencies and authorities into a new, streamlined MassDOT, which is a merger of the Executive Office of Transportation and Public Works (EOT) and its divisions with the Massachusetts Turnpike Authority (MTA), the Massachusetts Highway Department (MHD), the Registry of Motor Vehicles (RMV), the Massachusetts Aeronautics Commission (MAC), and the Tobin Bridge, currently owned and operated by the Massachusetts Port Authority (MPA). In addition, the MBTA and Regional Transit Authorities (RTA) are subject to oversight by the new organization. The organization also assumed responsibility for many of the bridges and parkways currently operated by the Department of Conservation and Recreation (DCR).

EPA is proposing to approve these administrative changes, which do not interfere with attainment and reasonable further progress or any other applicable Clean Air Act requirement, and which will, if finalized, make the SIP consistent with State agency organization.

III. Proposed Action

EPA is proposing to approve Massachusetts' revised 310 CMR 7.36, ''Transit System Improvements,'' submitted on November 6, 2013, as a revision to the Massachusetts SIP. This revised rule: (1) Deletes the existing SIP requirement to design the Red Line/Blue Line Connector from the Blue Line at Government Center to the Red Line at Charles Station (310 CMR 7.36(2)(i)); (2) lengthens by fifteen days the time within which MassDEP must hold a public meeting to take public comment on MassDOT's annual update and status report (310 CMR 7.36(7)(b)); and (3) replaces references to Executive Office of Transportation and EOT with references to Massachusetts Department of Transportation and MassDOT, respectively.

EPA's review of the material submitted on November 6, 2013 to remove the ''design only'' of the Red Line/Blue Line Connector from the Massachusetts SIP; add administrative changes to lengthen portions of the public process under 310 CMR 7.36(2)(i); and update references to the appropriate State transportation agency, indicates that the proposed modifications would not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable Clean Air Act requirement.

EPA is soliciting public comments on the issues discussed in this notice or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to the EPA New England Regional Office listed in the **ADDRESSES** section of this **Federal Register**.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*); does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: November 6, 2014.

Deborah A. Szaro,

Acting Regional Administrator, EPA New England.

[FR Doc. 2014–28299 Filed 11–28–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122, 123, 127, 403, 501, and 503

[EPA–HQ–OECA–2009–0274; FRL–9908–58–OECA]

RIN 2020–AA47

NPDES Electronic Reporting Rule

AGENCY: Environmental Protection Agency.

ACTION: Request for further comment.

SUMMARY: On July 30, 2013, the Environmental Protection Agency (EPA) proposed the NPDES Electronic Reporting Rule that would require electronic reporting instead of current paper-based NPDES reports. This action would modernize NPDES reporting, save time and resources for regulated entities and regulatory agencies, better protect the Nation's waters by improving compliance, and provide the public with access to information that affects their communities. The proposal would enhance transparency and accountability by providing regulatory agencies and the public with more timely, complete, accurate, and nationally-consistent data about the NPDES program and potential sources of water pollution. The benefits of this proposed rulemaking should allow NPDES-authorized programs in states, tribes, and territories to shift precious resources from data management activities to solving issues that threaten human health, water quality, and noncompliance issues. As a result of comments received on the proposed rule, we are soliciting further comments by opening a new public comment period.

DATES: Comments must be received on or before January 30, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OECA–2009–0274 by one of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: docket.oeca@epa.gov,* Attention Docket ID No. EPA–HQ–OECA–2009–0274.
- *Mail:* Send the original and three copies of your comments to: U.S. Environmental Protection Agency, EPA Docket Center, Enforcement and Compliance Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW., Washington, DC 20460, Attention Docket ID No. EPA–HQ–OECA–2009–0274. In addition, if applicable, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St. NW., Washington, DC 20503.
- *Hand Deliver:* Deliver your comments to: EPA Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC, 20004, Attention Docket ID No. EPA–HQ–OECA–2009–0274. Such deliveries are only accepted during the EPA Docket Center's normal hours of operation and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OECA–2009–0274. EPA's policy is that all comments received by the deadline will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it within the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment, and, if applicable, with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters and any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, please visit the EPA Docket Center homepage at *http://www.epa.gov/dockets/.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard-copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard-copy at the Enforcement and Compliance Docket in the EPA Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC, 20004. 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 Docket for the Office of Enforcement and Compliance Assurance (OECA) is (202) 566–1752. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and are subject to search. Visitors will be provided an EPA visitor's badge that must be visible at all times in the building and returned upon departure. The ''User Guide to the Docket for the NPDES Electronic Reporting Rule [DCN 0104]'' provides easy to follow instructions on how to access documents through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information, please contact Messrs. Andrew J. Hudock (202–564–6032) or Carey A. Johnston (202–566–1014), Office of Compliance (mail code 2222A), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC, 20460; email addresses: *hudock.andrew@epa.gov* or *johnston.carey@epa.gov.*

SUPPLEMENTARY INFORMATION:

How is this document organized?

The outline of this document follows the following format:

I. General Overview of the Supplemental Notice and Proposed Rule
II. Overview of Public Comments
III. Discussion of Key Issues Identified in Public Comments
IV. Matters for Which Comments Are Sought
V. Outreach
VI. Executive Orders 12866 and 13563

I. General Overview of the Supplemental Notice and Proposed Rule

A. Supplemental Notice

The U.S. Environmental Protection Agency (EPA) proposed the National Pollutant Discharge Elimination System (NPDES) Electronic Reporting Rule on July 30, 2013 (78 FR 46005). The rule is explained in greater detail below. EPA received many comments on the proposed rule, from a variety of

stakeholder groups, and the comments were generally supportive of electronic reporting as modern and efficient. However, some comments raised issues regarding aspects of the proposed implementation and operation of the rule. In this supplemental notice, EPA is soliciting additional comment on the following issues raised by commenters: (1) Initial recipient status; (2) the use of the State Readiness Criteria and the possibility of EPA requiring the electronic submission of NPDES program data to EPA when authorized states, tribes, and territories have not successfully implemented electronic reporting; (3) implementation plan schedule; (4) copy of record; and (5) modifications of state NPDES regulations and statutes. We are also soliciting comment on Cross-Media Electronic Reporting Rule (CROMERR) implementation, electronic reporting for the Concentrated Animal Feeding Operations (CAFOs) and stormwater sectors, and the economic analysis.

EPA will consider comments on any other aspects of the proposed rule. This notice opens a new public comment period. This notice is an opportunity for EPA to identify key issues raised by comments, clarify any misunderstandings about the proposed rule, and discuss possibilities for how EPA might modify the rule to address issues raised by stakeholders. This notice is not, however, intended to respond to all comments submitted; EPA will respond to all substantive comments when it takes final action on the proposed rule. There is no need to re-submit comments already submitted to EPA's docket for the proposed rule.

B. Proposed Rule

Pursuant to the Clean Water Act (CWA), 33 U.S.C. 1251 et. seq., the U.S. Environmental Protection Agency (EPA) proposed the National Pollutant Discharge Elimination System (NPDES) Electronic Reporting Rule on July 30, 2013 (78 FR 46005). The proposed rule does not add to what is currently required to be reported by regulated entities under the existing Federal NPDES program regulations; it would only change how that information is to be reported. In particular, the proposed rule would substitute electronic reporting for certain paper-based reports. Over the long term, this should save time and resources for regulated entities, states, tribes, territories, and EPA while improving compliance and better protecting the Nation's waters. The proposed rule would require regulated entities and regulators to use existing, available information technology to electronically report information and data related to the NPDES program in lieu of filing paper reports.

The proposed rule would allow improvements to be made to the transparency and usefulness of information about regulated entities and permitting, compliance, and enforcement activities in each state through the use of available technology to electronically report facility, discharge, monitoring, compliance, and enforcement data; and providing more complete, accurate, and timely data to the public. Improving public access to this timely and complete information would help inform and empower communities. EPA is soliciting comment on how to improve public accessibility and usability of the data. EPA notes that this proposed rule does not change the Agency's public disclosure regulations (40 CFR 2).

This proposed rule would require that certain reports currently submitted on paper (*i.e.,* Discharge Monitoring Reports (DMRs), Notices of Intent to discharge in compliance with a general permit, other general permit waivers, certifications, and notices of termination of coverage, and some program reports) be submitted electronically by NPDES-regulated entities to EPA through EPA's Central Data Exchange (CDX) or to the authorized state, tribe, or territory NPDES program, or to EPA through EPA's Central Data Exchange (CDX). Importantly, while the proposed rule changes the method by which information on NPDES notices of intent for coverage under general permits, facility discharges, monitoring of compliance, facility reports, and enforcement responses is provided (*i.e.,* electronic rather than paper-based), it does not increase the amount of information required from NPDES-regulated entities under existing regulations. Similarly, though it changes the method through which citizens may access this information, this rule only affects information already required by law to be available to the public.

States, tribes, and territories that are authorized to implement the NPDES program are the unique sources of certain key information regarding the regulated facilities. For example, states have facility information from NPDES individual permit applications, permit information including limits and permit conditions, compliance determination information including that from inspections, and enforcement response information. Under this proposed regulation, authorized NPDES programs would be required to share this NPDES program implementation information electronically with EPA.

The proposed rule, in conjunction with EPA's current public data access tools, would provide a more complete and easily accessible set of facility, permit, compliance, and enforcement data to the public. This would provide a powerful incentive for government and regulated entities to maintain and improve their performance. This can elevate the importance of compliance information and environmental performance within regulated entities and provide an opportunity for them to quickly address any noncompliance. This can also improve access to permit and compliance and enforcement action data in emergency situations (see DCN 0105). It provides the opportunity for two-way communication between regulatory agencies and regulated facilities to immediately address data quality issues and to provide compliance assistance or take other action when potential problems are identified. Complete and accurate data would also allow EPA to evaluate performance across authorized programs.

The requirement of electronic reporting of NPDES information is expected to result in reductions in burden and transaction costs. Tracking data electronically is less expensive, more efficient, more accurate, and better able to support program management decisions than paper tracking (see July 30, 2013; 78 FR 46015–17).

II. Overview of Public Comments

EPA received 170 public comments on the proposed rule from a variety of stakeholder groups. The comments were generally supportive of electronic reporting as modern and efficient, but raised issues regarding aspects of the proposed implementation and operation of the rule. Table II–1 provides an overview on the public comments on the proposed rule. The largest number of public comments (by pages) came from government agencies with industrial stakeholders contributing most of the remaining comments. Many of the industrial comments came from the agricultural sector.

TABLE II–1—NUMBER OF PUBLIC COMMENTS: SUBMISSIONS, PAGES, AND COMMENT EXCERPTS

Commenter type	Number of submissions	Number of comment pages
Anonymous or Individual Person	32	44
Environmental Advocacy Organization	3	22
Government (Local)	28	114
Government (State)	39	308
Government (Federal)	2	5
Industry (Misc.)	39	188
Industry (Agriculture)	25	163
Industry (Software Vendors)	2	6
Total	170	850

EPA has reviewed all of these comment submissions and identified the key issues raised by commenters. The following sections describe some of these key comments in more detail.

III. Discussion of Key Issues Identified in Public Comments

A. Implementation Plan

EPA received many comments from states and NPDES-regulated entities on the proposed implementation plan and is considering possibilities to address these concerns. Most of these comments focused on the following issues: (1) Initial recipient status; (2) the use of the State Readiness Criteria and the possibility of EPA requiring the electronic submission of NPDES program data to EPA when authorized states, tribes, and territories have not successfully implemented electronic reporting; (3) implementation plan schedule; (4) copy of record; and (5) modifications of state NPDES regulations and statutes. Complete details on the implementation plan are in the proposed rule (July 30, 2013; 78 FR 46047). The following are the most frequently discussed issues related to the implementation plan.

1. Initial Recipient Status

Some comments evidenced confusion about the concept of the 'Initial Recipient,' a term defined in the proposed rule at 40 CFR 127.2(b). EPA would like to provide some additional clarity in this supplemental notice. In general terms, the Initial Recipient is the first to receive electronically reported NPDES program data and could be the authorized state, tribe, or territorial NPDES program or EPA. The proposed rule also requires authorized NPDES programs and EPA to share NPDES program data (*i.e.,* Appendix A to Part 127) with each other on a regular schedule.

Under the proposed rule, NPDES-regulated entities would submit NPDES program data to the designated initial recipient. EPA's goal is to help all states be the initial recipient for any data group (*e.g.,* DMRs) for which they would like to first receive the data. In the proposed rule, Section 127.27 outlines the process for requesting the designation of initial recipient.

- An authorized state, tribe, or territory may request to be the initial recipient of electronic NPDES information from NPDES-regulated facilities for specific NPDES data groups by submitting a request to EPA. [Section 127.27(a)]
- This request shall identify the specific NPDES data groups for which the state, tribe, or territory would like to be the initial recipient of electronic NPDES information, a description of how its data system will be compliant with 40 CFR part 3 and 40 CFR part 127, and the date or dates when the state, tribe, or territory will be ready to start receiving this information.

There is also a process in Section 127.27(d) for helping states become the initial recipient. As noted in the proposed Section 127.27(d)(4), EPA will ''work with the Director of the authorized NPDES program to remediate all issues identified by EPA that prevent the authorized NPDES program from being the initial recipient. When all issues identified by EPA are resolved and the authorized state, tribe, or territory is the initial recipient, EPA shall update the initial recipient listing in 127.27(c) and publish this listing on its Web site and in the **Federal Register**.''

Comments on the Initial Recipient term came from state and local governments, as well as from NPDES-regulated entities. Most of these commenters misunderstood the Initial Recipient designation as being contingent on the State Readiness Criteria. The following discussion explains the relationship between these two related but distinctly different terms. The term ''initial recipient'' means the governmental entity, either the state or EPA, who *first* receives the electronic reports. EPA proposed to maintain the initial recipient list for each state and each NPDES data group and publish this list on its Web site and in the **Federal Register**. EPA's decision to designate an authorized state, tribe, or territory as the initial recipient for NPDES program data is limited to the authorized program's description of ''how its data system will be compliant with 40 CFR part 3 and 40 CFR part 127, and the date or dates when the state, tribe, or territory will be ready to accept NPDES information from NPDES-regulated facilities in a manner compliant with 40 CFR part 3 and 40 CFR part 127'' [see 40 CFR 127.27(a)]. By contrast, the ''State Readiness Criteria'' are used when EPA is deciding whether to require electronic reporting through an Information Collection Request (see July 30, 2013, 78 FR 46048). The 90 percent participation rate aspect of the State Readiness Criteria would *not* affect EPA's determination of the Initial Recipient as detailed in Section 127.27. For example, a state can be listed as the Initial Recipient for receiving DMRs even if the electronic DMR participation rate in that state is less than 90 percent.

EPA proposed using **Federal Register** notices and its Web site to provide notification to NPDES-regulated entities of the Initial Recipient status for each data group for each state. Commenters noted that EPA should improve this proposed notification system (*e.g.,* notice by registered mail) because some NPDES-regulated entities (*e.g.,* operators under the Construction General Permit) may not be aware of the **Federal Register** notices or EPA's Web site. They also noted that many regulated entities granted a temporary waiver from the proposed rule would not have the technology to gain access to these notification systems. EPA is soliciting comment on additional means for providing notice on the Initial Recipient status. See Section IV of this notice.

Finally, states requested clarification that they can obtain Initial Recipient

status after the implementation phase of the rule (*i.e.,* more than 120 days after the effective date of the final rule). See Section 127.27(a). EPA intends to make it clear in the final rule that a state NPDES program can initially elect for EPA to be the Initial Recipient and then at a later date seek EPA approval to change the initial recipient status from EPA to the authorized state, tribe, or territory. EPA would like to provide this flexibility to NPDES programs as EPA's preference is to defer to the authorized NPDES programs on how the NPDES program data from regulated entities should be routed when electronic reporting can be properly implemented (*e.g.,* use of CROMERR-compliant tools). EPA is focused on changing NPDES reporting from paper submission to proper electronic submissions, not in becoming the Initial Recipient.

2. State Readiness Criteria

Under the proposal, a complete set of electronic information for the regulated universe covered by this proposed rule would be required two years after the effective date of the final rule. The Agency would seek to collect these data directly from NPDES-regulated facilities only if not already being submitted electronically to the authorized state, tribe, or territory given the importance of complete, timely, and accessible NPDES program data to EPA states, tribes, territories, and the public.

EPA proposed three factors for the ''State Readiness Criteria,'' which EPA would use to determine when to ''fill in the gaps'' where NPDES-regulated entities are not yet fully reporting electronically edit NPDES program data:

(1) *Participation Rate:* The authorized state, tribe, or territory has 90 percent participation rate by data group (*i.e.,* NPDES-regulated entities submit timely, accurate, complete, and nationally consistent NPDES data using the NPDES program's electronic reporting systems for a data group such as DMRs); and

(2) *Approved Electronic Reporting Systems:* The electronic reporting systems used by the NPDES-regulated entity meet all of the minimum Federal reporting requirements for 40 CFR 3 (CROMERR) and 40 CFR 127 (NPDES Electronic Reporting Rule); and

(3) *Initial Recipient Status:* EPA lists the state, tribe, or territory as the initial recipient for electronic NPDES information from NPDES-regulated entities on EPA's Web site. Each authorized program will then designate the specific tools for these electronic submissions from their permittees. These designations are proposed to be made separately for each NPDES data group (see 40 CFR 127.2(c) and 127.27).

In order to provide clearer distinction between the Initial Recipient and State Readiness Criteria terms, EPA solicits comment on eliminating the third factor in the State Readiness Criteria (*i.e.,* Initial Recipient Status). The first and second factors in the State Readiness Criteria clarify that EPA's collection of the data will be based on the participation rate and the use of CROMERR compliant tools.

As a means to ''fill in the gaps'' where NPDES-regulated entities are not yet reporting electronically, EPA is considering using its authority under CWA sections 101, 304(i), 308, 402(b), and 501 to require NPDES-regulated entities to electronically report NPDES program data to EPA. As proposed, EPA would use its existing authority under the CWA and current technology to facilitate electronic reporting using CWA authority and an Information Collection Request (ICR) to directly collect information from NPDES-regulated entities that are not participating in state electronic reporting according to the proposed rule's implementation schedule. EPA anticipates this will not be a widespread occurrence as electronic reporting, over the long term, reduces burden for the reporter. If we encounter widespread non-compliance with the electronic reporting requirements, EPA will take that as a signal to evaluate the issue. EPA estimates that any use of this ICR will taper off over time as more NPDES-regulated entities utilize electronic reporting and as we learn more about electronic reporting. As previously noted, EPA electronically collecting these data from a subset of entities is independent of the Initial Recipient status of the authorized state, tribe, or territory. Authorized NPDES programs remain the data steward for any NPDES program data that they collect electronically or on paper. Under this proposal, EPA would be the data steward for the data it directly collects and will be responsible for resolving any data discrepancies.

EPA received comments from state programs and regulated entities that were concerned about EPA's proposal to require electronic reporting directly to EPA where progress in electronic reporting to the state was not meeting the expected level. In particular, state programs noted the increased burden of the potential double reporting (such as paper submission of DMR to state, electronic submission to EPA) and the potential of conflicting data between the two submissions, roles of the state or EPA data stewards, and confusion over which submission is the 'copy of record'). States appeared interested in participating in electronic reporting and pursuing some level of state readiness approval, but expressed concern about how long it might take to meet the 90 percent threshold for some data groups. One commenter noted that during the interim period, differing initial recipients for various data groups could be complicated or burdensome for some facilities.

In particular, states noted that they will likely not meet the 90 percent participation factor in the State Readiness Criteria within the proposed rule's two-year implementation schedule. Commenters noted difficulties in seeking and obtaining CROMERR approval for their electronic reporting systems as well as difficulties in outreach and training for the large number of NPDES-regulated entities that will need to switch from paper to electronic reporting. EPA seeks comment on whether it should wait longer after the effective date of the final rule to begin evaluating participation rates. One commenter suggested gradually phasing in the participation rate factor in the State Readiness Criteria as follows: Participation rate of 30 percent by the end of the first year, 60 percent by the end of the second year, and 90 percent by the end of the third year. EPA also seeks comment on this approach. EPA also seeks comment on whether, under one of the options above, it should maintain the current one-year schedule for the DMR data flow since many states and NPDES permittees are using NetDMR and eDMR tools. EPA is considering the possibility of a phased approach and solicits comment on the option of maintaining the one year schedule for the DMR data flow as well as a phased approach to measure participation rate as part of the State Readiness Criteria.

One state suggested that if the 90 percent participation factor is not met, EPA should use its CWA authority through use of an ICR to compel NPDES-regulated entities to electronically submit their NPDES program data to the authorized state, tribe, or territory rather than directly to EPA. The commenter also suggested that the authorized state, tribe, or territory could use its enforcement discretion to refrain from enforcing conditions in the permit or other control mechanisms [1] that specify paper reporting as long as the regulated entity successfully reports its data electronically using the appropriate CROMERR-approved electronic reporting system. This would

[1] Some NPDES-regulated entities (*e.g.,* biosolids generators with no discharge, categorical industrial users) may not have an NPDES permit. These entities are controlled through direct application of EPA regulation or may be controlled through state regulation or other actions.

enable EPA and authorized states, tribes, and territories to realize the benefits of electronic reporting without requiring double reporting from regulated entities and coordinating two separate submissions.

Another state commenter also suggested that EPA calculate for each authorized NPDES program one DMR electronic submission participant rate for individually permitted facilities and another DMR electronic submission participant rate for facilities covered under general permits. The commenter suggested that there are important differences between individually permitted facilities, which tend to be the larger facilities with a continuous discharge like POTWs, and facilities covered under general permits, which tend to be more numerous and include construction stormwater sites that might need only temporary NPDES permit coverage. Some states also use different state agencies to manage specific industrial sectors (*e.g.,* construction stormwater, mines, CAFOs) and these industrial sectors are often covered by general permits. EPA solicits comment on all of these potential alternatives (see Section IV).

With respect to the comment that the reporting environment could be complicated for some facilities if the state has not qualified as the initial recipient for all data groups, EPA notes that many NPDES-regulated entities currently submit NPDES program data to different agencies. For example, most states are not authorized to implement the Federal Sewage Sludge program (40 CFR 503) and many POTWs in these states are required to submit DMR data to the state and the Annual Biosolids Program Report to EPA. Under the proposed rule, EPA would list the initial recipient for each data group for each state in the **Federal Register** and on its Web site so that regulated entities know to whom to submit their information. In addition, as noted in the proposal, EPA solicits comment on changing its regulations governing the standard conditions applicable to all NPDES permits by adding a new standard permit condition [see 40 CFR 122.41(l)(9)] that would require NPDES-regulated facilities to ensure that, for each type of electronic NPDES submission, the information is sent to the appropriate initial recipient, as identified by EPA, and as defined in 40 CFR 127.2(b). Authorized NPDES programs would include this requirement in all permits and control mechanisms.

Below are a few examples of how the proposed rule uses the Initial Recipient and State Readiness Criteria terms and more examples are in the docket (DCN 0106).

Example #1: EPA lists State X as being the Initial Recipient for DMRs and there are 1,000 facilities in this state that are required to submit DMRs. One year after the effective date of the final rule, 900 facilities in this state are correctly electronically submitting DMRs to the state (*i.e.,* these DMRs contain all Appendix A data and are submitted in compliance with CROMERR). What actions will EPA take with respect to the 100 facilities that submitted their DMRs on paper to the state?

Answer: Under the proposed rule, EPA would take no actions to require electronic submissions of DMRs from these facilities because 90 percent of the facilities in this state that are required to submit DMRs are electronically submitting these DMRs in compliance with Part 127 (Appendix A data included) and Part 3 (CROMERR—authentication and encryption standards). The electronic DMR submission to the state is the copy of record for the 900 facilities and the paper DMR submission to the state is the copy of record for the 100 facilities.

Example #2: Assume the same scenario as in Example #1 but now only 750 facilities in this state are correctly submitting DMRs to the state one year after the effective date of the final rule. What actions will EPA take with respect to the 750 facilities in this state that are correctly electronically submitting DMRs to the state and the 250 facilities that submitted their DMRs on paper to the state?

Answer: Under the proposed rule, EPA would take no actions to electronically collect DMRs from the 750 facilities that are electronically submitting these DMRs in compliance with Part 127 (Appendix A data included) and Part 3 (CROMERR—authentication and encryption standards) to the state as the Initial Recipient for DMRs. However, since the DMR electronic submission participation rate is less than 90 percent, EPA would use its CWA authority through use of an ICR to require electronic submission of DMR data from the 250 facilities who submitted their DMRs using paper reports. This means that these 250 facilities will be potentially filing their DMR twice: Once on paper to the state (if required by their permit) and another time to EPA electronically. Once a facility is electronically submitting its DMRs to the state, the facility no longer is required to electronically report its DMRs directly to EPA. Additionally, tA01DE2.he electronic DMR submission to the state is the copy of record for the 750 facilities and the paper DMR submission to the state is the copy of record for the 250 facilities. EPA also notes that authorized NPDES programs can help increase electronic reporting (and lower the instance of double reporting) by modifying or reissuing NPDES permits to include electronic reporting. EPA has proposed to allow authorized NPDES programs to do this through the minor modification process (see 40 CFR 122.63).

Example #3: Assume the same scenario as in Example #2 but, after some efforts by the state and EPA, the DMR electronic submission participation to the state is now at or above 90 percent. What actions will EPA take with respect to the 100 or fewer facilities that submitted their DMRs on paper to the state?

Answer: This is the same answer for Example #1.

Example #4: State X initially requests that EPA be the Initial Recipient for DMRs and there are 1,000 facilities in this state that are required to submit DMRs. One year after the effective date of the final rule 900 facilities in this state are correctly electronically submitting DMRs to EPA. What actions will EPA take with respect to the 100 facilities that submitted their DMRs on paper to the state?

Answer: This is the same answer for Example #1.

Another important consideration is that NPDES-regulated entities with temporary waivers are excluded from the State Readiness Criteria participation calculations. For example, if State X has 1,020 facilities that are required to submit DMRs and 20 of these facilities are granted temporary waivers from electronic reporting, then as a group at least 900 of the 1,000 DMR-submitting facilities without waivers [$= 0.9 \times (1{,}020 - 20)$] need to electronically submit DMRs to State X in order to meet the DMR electronic submission participation threshold of 90 percent.

3. Implementation Plan Schedule

EPA proposed two phases for the implementation of electronic reporting with the first phase starting one year after the effective date of the final rule. Prior to this date, EPA will also work with authorized NDPDES programs in order to collect the necessary facility and permit that supports electronic reporting. These necessary facility and permit data include data on facilities covered by general permits so that these general permit covered facilities can electronically submit their DMRs to their permitting authority and these permitting authorities can share these data with EPA. Likewise, EPA will also work with states to collect the necessary data to support electronic reporting for the second phase.

• *Phase 1 Data (one year after the effective date of the final rule):* EPA would electronically receive basic facility and permit information as well as state performance data including inspections, violation determinations, and enforcement actions. Additionally, EPA and states would electronically receive: (1) DMR information (if required by the NPDES permit) from NPDES-regulated entities; and (2) general permit reports [Notice of Intent to be covered (NOI); Notice of Termination (NOT); No Exposure Certification (NEC); Low Erosivity Waiver (LEW)] from facilities covered by Federally-issued general permits.

• *Phase 2 Data (two years after the effective date of the final rule):* In addition to Phase 1 data, EPA and states would receive: (1) General permit reports from facilities covered by state-issued general permit; and NPDES program reports (*e.g.,* CAFO Annual Report, Pretreatment Program Annual Report).

As noted in the previous section of this notice, many states indicated that they likely would not be able to implement electronic reporting within two years of the effective date of the final rule. One commenter suggested that EPA should consider working with states to develop individual state plans with varying schedules for implementation based on each state's readiness and resources to implement electronic reporting. Another suggestion was to integrate electronic reporting into the permit requirements in the next permit cycle, as permits are reissued. Other commenters suggested extending the implementation plan beyond two years. EPA also solicits comment on these alternatives.

Adding additional phases or time could include pushing the timing of Phases 1 and 2 back by a certain amount of time, or including additional phases for certain program areas. For instance, MS4 program reports could be moved to a third phase to give states and EPA more time to determine how best to incorporate these reports into an electronic format.

As noted in the proposed rule, using the NPDES permit cycle to implement electronic reporting would mean NPDES program data would not be fully available across all permits and states until 2022 at the earliest. Using the NPDES permit cycle to implement electronic reporting would mean that electronic reporting requirements would be incorporated into NPDES permits as they are re-issued. Using this approach would also mean that it would take approximately seven years to have data across all permits and states as authorized states, tribes, and territories will need two years to update their statutes and then it would take an additional five years for one NPDES permit cycle.[2] Additionally, there are a number of NPDES permits that are administratively continued with some permits that are ten or more years old (see DCN 0107). EPA identifies permits that are administratively continued beyond their expiration date as ''backlogged.'' EPA solicits comment on the option of EPA using its CWA authority through use of an ICR to require facilities operating under backlogged permits to electronically submit their NPDES program data.

As noted in the proposed rule, EPA considered but did not choose the permit renewal cycle as a means to phase in electronic reporting as that approach would delay significant benefits of electronic reporting (*e.g.,* state savings and expedited access to complete NPDES program data in an electronic format for EPA, states, tribes, and territories, regulated entities, and the public).

With respect to individual state implementation plans, if EPA were to chose this option EPA would likely establish a schedule for when these plans were due, the criteria it would use to review these plans, and the time period for states to submit subsequent revisions. EPA would look to see that each of these plans provides enough detail (*e.g.,* tasks, milestones, roles and responsibilities, necessary resources) to ensure that EPA and states can work together to successfully implement electronic reporting. The details likely necessary for these plans include identifying: (1) All tasks for capturing and electronically processing facility and permit data; (2) all tasks for updating any state data systems; (3) technologies for electronic reporting systems and any necessary CROMERR approval; (4) technologies for transmitting and receiving Appendix A data to and from EPA; (5) schedule for updating state statutes, regulations, and NPDES permits; (6) schedule for training NPDES regulated entities on how to utilize electronic reporting systems; (7) roles and responsibilities; and (8) necessary resources and commitments. These implementation plans would need to be approved by the authorized NPDES Director (as defined in 40 CFR 122.2). Under this option, EPA would use these plans to ensure all states are moving to electronic reporting as expeditiously as possible. EPA would also limit the amount of time that it will provide to states for full implementation, as EPA would like all stakeholders to realize the many benefits of electronic reporting in a timely manner. Finally, EPA would ask states to create contingencies in their implementation plans that might rely on EPA services and systems (*e.g.,* NetDMR, NeT) if the state continually misses its own scheduled milestones.

[2] See 40 CFR 123.62(e).

4. Copy of Record

Several comments asked for clarification on how EPA's proposed rule will affect the ''copy of record'' for NPDES data submissions. EPA is clarifying that the proposed rule does not change EPA's authentication and encryption standards for electronic reporting. Below is a discussion of the copy of record as it pertains to the implementation of electronic reporting.

An important element of EPA's authentication and encryption standards for electronic reporting is the ''copy of record,'' which is ''a true and correct copy of an electronic document received by an electronic document receiving system, which copy can be viewed in a human-readable format that clearly and accurately associates all the information provided in the electronic document with descriptions or labeling of the information.'' See 40 CFR 3.3. A copy of record must:

• Be a true and correct copy of the electronic document that was received, and it must be legally demonstrable that it is in fact a true and correct copy;

• include all the electronic signatures that have been executed to sign the document or components of the document;

• include the date and time of receipt to help establish its relation to submission deadlines; and

• be viewable in a human-readable format that clearly indicates what the submitter and, where applicable, the signatory intended that each of the data elements or other information items in the document means.

For such CROMERR compliant submissions, the copy of record is intended to serve as the electronic surrogate for what is commonly referred to as the paper submission with a ''wet-ink'' signature. The copy of record is meant to provide an authoritative answer to the question of what was actually submitted and, as applicable, what was signed and certified in the particular case.

It is important to note that the use of an electronic reporting system may dictate where the electronic copy of record is retained. EPA's NetDMR and CDX for NeT contain the electronic copy of record for submissions made with these tools. Likewise, state electronic

reporting systems will contain the electronic copy of record for submissions made with these state tools.

Under certain scenarios, as described in the previous sections, EPA may electronically collect NPDES program data directly from NPDES-regulated entities and these entities may also be making a paper submission of the same report with a ''wet-ink'' signature to the state. In these cases, the paper submission to the state with a ''wet-ink'' signature is the copy of record.

5. Modifications of State NPDES Regulations and Statutes

Several commenters requested clarification on the relationship between the implementation of electronic reporting and the schedule for any necessary modifications of state NPDES regulations and statutes. As indicated in the proposed rule, EPA estimated that some states may need to update their regulations or statutes to make clear that electronic reporting is required for the reports listed in Table 1 of Appendix A and that these electronic submissions must be compliant with Part 127 (including Appendix A) and Part 3 (CROMERR—authentication and encryption standards). Existing EPA regulations at 40 CFR 123.62(e) require that any updates to the authorized NPDES program take place within one-year of the effective date of the final rule (if no state statute change is required) and within two years of the effective date of the final rule (if a state statute change is required).

These regulatory and statutory updates are unrelated to EPA's decision on who can be the Initial Recipient for NPDES program data. However, if a state regulation or statute prohibits or inhibits the electronic reporting of NPDES program data to the state, then this might lower the electronic reporting participation rate of NPDES-regulated entities. EPA will examine cases where there are low participation rates to determine the cause as there may be other issues beyond regulatory or statutory updates that need to be remedied. Under certain scenarios, as described in the examples above, these lower participation rates may lead EPA to electronically collect NPDES program data directly from NPDES-regulated entities when the entity is also making a paper submission of the same data to the state.

B. Cross-Media Electronic Reporting Regulation (CROMERR)

EPA's proposed rule (Part 127) requires that all electronic reporting systems that are used for implementing NPDES electronic reporting, whether already existing or to be developed by EPA and authorized NPDES programs, be compliant with EPA's Cross-Media Electronic Reporting Regulation (CROMERR).[3] CROMERR sets performance-based, technology-neutral standards for systems that states, tribes, and local governments use to receive electronic reports from facilities they regulate under EPA-authorized programs and requires program modifications or revisions to incorporate electronic reporting. CROMERR also addresses electronic reporting directly to EPA.

EPA received a number of comments on various aspects of applying for, receiving approval and authorization, and implementing an electronic reporting system that complies with CROMERR. The comments can be divided into two key categories: (1) The process for CROMERR application approvals; and (2) the technical requirements for signature authentication. There are also two additional comment areas that require clarification: (1) Whether a NPDES-regulated entity must submit a CROMERR application; and (2) EPA's requirement to change passwords at least once every 90 days.

1. Improving/Streamlining the Application Approval Process

The review and approval process for a CROMERR application allows 75 days for completeness review, and 180/360 days for new/existing systems for approval review. State and authorized program application preparation and amendments are not included in this timeframe. The actual timeframe may be shorter or longer. Many of the comments highlighted the seemingly conflicting timelines for implementation of the NPDES Electronic Reporting Rule with the CROMERR requirements. Commenters expressed concern that system development and CROMERR approval would not be possible within the 2-year rule implementation schedule and that authorized programs may not be able to maintain their status as the Initial Recipient of NPDES program data. Commenters also questioned whether they would be required to submit more than one CROMERR application if they rely on multiple tools for electronic reporting.

To address these concerns, EPA will be implementing several measures to streamline the CROMERR application submittal, review, and approval process.

- *Standard Checklists and Forms.* A standard checklist has been developed for EPA national systems (*e.g.,* NetDMR, NPDES Electronic reporting system (NeT), CROMERR shared services, Attorney General Statement, and Signature Agreements) that can be modified for those using these services. These applications require the authorized programs to complete a small amount of state-specific information. The timeframes for these approvals are generally reduced to between 16 to 20 weeks. See: *http://www.epa.gov/cromerr/tools/index.html* and DCN 0109. Additionally, the CROMERR approval process for states choosing to use EPA's NeT will have a significantly reduced approval process. EPA estimates that the approval process will be less than 60 days and with reduced submission requirements.
- *Model CROMERR Application.* There are approximately five model CROMERR applications that can be adopted by authorized programs. These models illustrate different CROMERR solutions that can be modified for another program's CROMERR implementation. Adopting a model CROMERR application will streamline the approval process to under 6 months. See: *http://www.epa.gov/cromerr/tools/index.html.*
- *CROMERR Assistance and Training.* EPA currently provides CROMERR assistance through online forms. EPA also provides direct help to prepare and complete the application as well as implement and integrate CROMERR services. In particular, for applicants that do not use the standard or model checklists and are building their own system, EPA has recently implemented a customer relationship management tool and additional technical support to provide triggers and reminders on due dates and actions to improve the timeframes. EPA intends to work with states to develop state specific plans on how to obtain CROMERR approval. See: *http://www.epa.gov/cromerr/training/index.html.* EPA is also creating a position that will interact with senior officials within the states and EPA by serving as the dedicated contact for states on the selection and implementation of the NPDES e-reporting tool, and serve as an advocate for states' CROMERR applications for the NPDES program from receipt to approval to ensure state applications are being addressed in a timely manner.

2. Technical Requirements for Signature Authorization

The second key area of CROMERR comments are the identity-proofing requirements for issuing electronic signature credentials. While the

[3] This EPA rule was promulgated in 2005 (see 40 CFR part 3).

majority of the comments in this area focus on the burden of maintaining paper copies of signature agreements, the time associated with conducting identity proofing, and the issuance of signature credentials, some stakeholders provided comments on the existing NPDES signatory requirements (40 CFR 122.22). EPA is not proposing to change the NPDES eligibility signatory requirements as these are beyond the scope of this rulemaking. The following are issues that relate to this NPDES Electronic Reporting Rule.

• *Burden associated with high processing costs.* EPA notes that all of the comments on the signature agreement requirements were based on the assumption of wet ink signatures on paper. However, EPA is now making available a paperless, real-time, electronic identity proofing service that reduces the application and validation time from days to minutes, and costs from dollars to cents. As noted above, as part of the Central Data Exchange (CDX) CROMERR services, electronic identity-proofing is available to regulatory authorities that do not wish to develop such a system of their own. This service can be invoked in a way that is transparent to the user and would allow users to begin using their electronic signature credentials in a single session.

• *Burden associated with high turn-over and infrequent reporting.* Electronic reporting systems can structure the agreements and the associated business processes so that only a single agreement is collected, once, from each user who is granted authority to electronically sign documents in the system. For EPA CDX systems, a user only has to register and complete the signature agreement once, and the credentials do not expire.[4]

3. CROMERR Requirements for a NPDES-Regulated Entity

EPA received comments from POTWs, particularly from California, asking whether they would need to become CROMERR-certified in order to undertake electronic reporting. EPA is using this notice to confirm that under this proposed rule NPDES-regulated entities (*e.g.,* POTWs) are *not* required to submit a CROMERR application to electronically report NPDES program data. It is the responsibility of the authorized NPDES programs receiving these electronically reported NPDES program data to obtain approval from EPA for their electronic reporting systems and processes in accordance with EPA's CROMERR requirements. Under the proposed rule, NPDES-regulated entities that electronically report their NPDES program data would use CROMERR-approved electronic reporting systems and processes. Authorized NPDES programs are responsible for submitting CROMERR applications for their electronic reporting system and NPDES-regulated entities are only required to complete the necessary signature requirements for that system.

EPA also notes that Subpart D of CROMERR requires that state, tribal or local government agencies (including POTWs) that receive, or wish to begin receiving electronic reports under their EPA-authorized programs (*e.g.,* CWA pretreatment program) must apply to EPA for a revision or modification of those programs and obtain EPA approval.[5] However, an important consideration is that the proposed rule does not require approved pretreatment programs to electronically collect NPDES program data from significant and categorical industrial users. Approved pretreatment programs may continue to collect NPDES program data from significant and categorical industrial users on paper or may elect to seek EPA approval for their CROMERR-compliant electronic reporting systems and processes.

4. EPA Password Reset Requirement

EPA also received comments on the 90-day password reset requirement, suggesting that this frequency is too short and would be a burden for infrequent reporters. The 90-day password reset requirement is not a CROMERR requirement; rather, it is a long standing EPA security requirement that is used for all of our internal and external systems. However, most electronic reporting systems allow users to perform a password reset when their password has expired. For example, a regulated entity that only uses an electronic reporting system once a year can reset their password at the time of their electronic submission. A regulated entity would not need to access the electronic reporting system throughout the year simply to retain an active password or have an active password to initiate a password reset operation.

5. Relationship Between CROMERR Requirements and the Initial Recipient Term

EPA also received comments on how the CROMERR requirements would affect the Initial Recipient requirements in the proposed rule (see Section 127.27). The following provides more explanation on the interaction between the CROMERR requirements and the Initial Recipient requirements in the proposed. If the Initial Recipient status for a particular state for a particular data group switches from the state to EPA, then the NPDES-regulated entities in that data group in that state would need to ensure they register with the appropriate CROMERR-compliant system. In this example, these NPDES-regulated entities would switch from using a state electronic reporting system to an EPA electronic reporting system (*e.g.,* NetDMR, NeT). Likewise, if the Initial Recipient status for a particular state for a particular data group switches from EPA to the state, then those NPDES-regulated entities in that data group in that state would switch from an EPA electronic reporting system to a state electronic reporting system.

C. Concentrated Animal Feeding Operations (CAFO) Sector

EPA is clarifying the effects of this proposed rule on CAFOs in response to comments received that reflect misunderstanding about the proposed rule. The proposed rule would only require CAFOs with NPDES permits to submit information to permitting authorities that the Clean Water Act already requires them to provide. See 33 U.S.C. 1342. Additionally, this information already is publicly accessible pursuant to the Clean Water Act and its implementing regulations. The proposed rule would simply modernize the format through which permitted CAFOs would submit certain types of information (*i.e.,* electronic submission as opposed to paper-based reporting). This modernized format should increase efficiencies for permitted CAFOs as well as regulators. Permitted CAFOs that lack suitable Internet access would be able to receive temporary waivers so that they would not be required to submit information electronically.

The following summary explains how the proposed rule would affect permitted CAFOs.

[4] Also note that once the single electronic signature agreement/credentials are established they can be used for reporting to multiple regulatory programs in addition to NPDES.

[5] For example, EPA recently approved of the City of Grand Rapids' (Michigan) request to revise its general pretreatment regulations to allow electronic reporting. See February, 13 2014, 79 FR 8701.

PERMITTED CAFO RESPONSIBILITIES

Type of submission	Submission format
Individual permit applications and attached nutrient management plans (NMPs).	There is *no change* for the owner or operator, as a CAFO that is applying for an NPDES permit can submit forms and information in a paper format to the permitting authority. The proposed rule requires only selected data on the individual NPDES permit application (see Appendix A) to be electronically shared between states and EPA.
Notices of Intent to discharge in compliance with a general permit (NOIs).	CAFOs seeking coverage under an NPDES general permit would electronically submit these NOIs, unless a temporary waiver is granted by the authorized NPDES program. The proposed rule requires only selected data on the NOIs (see Appendix A) to be electronically shared between states and EPA.
NMPs attached to general permit NOIs.	There is *no change* to the owner or operator, as CAFOs seeking coverage under an NPDES general permit can submit these data and information in a paper format to the authorized NPDES program. Authorized NPDES program may elect to electronically receive NMPs from CAFOs; however, this proposed rule does not require authorized NPDES programs to share these NMPs with EPA or require electronic submission of NMPs.
Annual reports and DMRs	Permitted CAFOs would electronically submit these compliance monitoring data, unless a waiver is granted by the authorized NPDES program. The proposed rule requires only selected data on the annual reports and DMRs (see Appendix A) to be electronically shared between states and EPA.

The following summary lists the only changes the proposed rule would make in authorized NPDES program responsibilities.

AUTHORIZED NPDES PROGRAM (GENERALLY STATES) RESPONSIBILITIES

Type of submission	Submission format
Individual permit applications	Submit data listed in Appendix A to Part 127 electronically to EPA.
Inspection, violation determination, and enforcement action information	Submit data listed in Appendix A to Part 127 electronically to EPA.

As indicated in the tables above, contrary to concerns raised by some commenters, this proposed rule would not require electronic submission of NMPs. Nor would the proposed rule require NPDES-permitted CAFOs to submit any new information beyond what is already required in the current regulations.

In response to comments made expressing concerns that the proposed rule could infringe on the privacy of NPDES-permitted CAFO owners and operators or the facility, their employees or family members, EPA emphasizes that this rule would not require any information to be disclosed that is not already available to EPA and the public pursuant to existing legal requirements. *See, e.g.,* 33 U.S.C. 1318, 1342(j); 40 CFR 122.21(f). Information that permitted CAFOs submit on their permit applications is required to be publicly available pursuant to CWA section 402(j), which requires that ''[a] copy of each [NPDES] permit application and each [NPDES] permit . . . be available to the public. Such permit application or permit, or portion thereof, shall further be available on request for the purpose of reproduction.'' See 33 U.S.C. 1342(j). Section 402(j) applies to all NPDES permit applications, including CAFO NPDES permits. In addition, CWA section 402 requires that states, tribes, and territories implementing NPDES programs provide for ''public . . . notice of each application for a permit and provide an opportunity for public hearing before a ruling on each such application.'' See 33 U.S.C. 1342(a)(1), (b)(3).

Agricultural stakeholders also stated their concerns that a public national database with the location information of livestock operations could increase the risk of acts of terrorism at such operations. EPA notes that all of the information proposed to be submitted electronically is already publicly available today. The proposed rule is focused on modernizing existing reporting requirements by moving from paper to electronic submissions. The proposed rule does not change the data and information that NPDES-regulated entities are required to report or how EPA manages these data and makes it available to the public. Existing law requires that information submitted in connection with a permit application, as well as other effluent data, be available to the public. Permitted CAFOs and other sectors have been regulated under the NPDES program for over 40 years and permitted entities like CAFOs have been required to submit individual NPDES permit applications or NOIs for coverage under a NPDES general permit like any other facility seeking permit coverage. The proposed rule is only to modernize the data processed from paper to computer to make the program more efficient and effective.

Existing law also requires authorized NPDES programs (usually states) to share NPDES program information with EPA. Authorized NPDES programs are required to ''keep such records and submit to the Administrator such information as the Administrator may reasonably require to ascertain whether the State program complies with the requirements of CWA or of this part.'' 40 CFR 123.43(d). *See also* 40 CFR 123.41(a) (''Any information obtained or used in the administration of a state program shall be available to EPA upon request without restriction.'').

Pursuant to EPA's NPDES data sharing policy, which dates back to 1985, authorized NPDES programs share data, including the following data, with EPA's national NPDES program database for all NPDES-regulated entities (major and non-major facilities): facility name; SIC code(s), facility address, city, state, and zip code; facility latitude and longitude, facility owner's first and last name and full mailing address. For example, EPA makes these data available now through its ECHO Web site (*http://echo.epa.gov*) and Envirofacts (*http://www.epa.gov/enviro/*).

EPA did not propose any changes to the way in which it protects confidential business information (CBI) in implementing electronic reporting. It is long-standing existing law that information required by an NPDES application form may not be claimed confidential. 40 CFR 122.7(b) and (c).

With respect to CAFO Annual Program Reports, EPA discussed how it will handle claims of CBI for these data in the 2003 CAFO rule (February 12, 2003, 68 FR 7233). In particular, the 2003 CAFO rulemaking states:

EPA expects that the permitting authority will make this information available to the public upon request. This should foster public confidence that CAFOs are complying with the requirements of the rule. In particular, the information in the annual report will confirm that CAFOs have obtained coverage under an NPDES permit, are appropriately controlling discharges from the production area, and have developed and are implementing a nutrient management plan . . . Under the existing regulations at 40 CFR part 2, subpart B, a facility may make a claim of confidentiality for information it must submit and EPA must evaluate this claim if it receives a request for the information from the public . . . Claims of confidentiality with respect to information submitted to the State will be processed and evaluated under State regulations.

The proposed NPDES Electronic Reporting rule does not change the long-standing procedures for dealing with public and confidential information in the existing NPDES regulations. Additionally, EPA has the capability of electronically collecting CBI through EPA's CDX system and may use this capability to allow NPDES permitted CAFOs to securely submit their CAFO Annual Program Reports.[6]

Some commenters raised questions about the authority of states and EPA to inspect CAFOs. Section 308 of the CWA authorizes inspections of premises where effluent sources are located, 33 U.S.C. 1318(a)(B), and data gathering from point sources that discharge or may discharge, 33 U.S.C. 1318(a)(A), even if those facilities are not required to have a permit because they do not discharge. See also 33 U.S.C. 1342 (requiring that authorized state programs have the same authority to inspect, monitor, enter, and require reports as section 308 of the Act). States and EPA gather information from point sources, including CAFOs, that discharge pollutants or may discharge pollutants for a variety of purposes, including determining compliance with applicable effluent limitations and verifying that the CAFO is not in fact discharging without a permit. *See* 33 U.S.C. 1318.

Stakeholders raised concerns about EPA posting information on unpermitted CAFOs and AFOs on EPA's public Web site. The Clean Water Act specifically identifies concentrated animal feeding operations as a type of ''point source.'' See 33 U.S.C. 1362(14). The NPDES permit program regulates discharges of pollutants from point sources. It is important for authorized NPDES programs (generally states) to report inspection information on all facilities (permitted or unpermitted) to EPA, as they currently do, so that EPA can know that the state has inspected the facility and found either that there is no discharge and no permit is required or there is a discharge and a possible violation. This reporting also benefits the facility because it avoids a possibly duplicative EPA inspection.

In order to address comments regarding the privacy interests of an unpermitted CAFO and AFO that an authorized state NPDES program or EPA has assessed and found to have not violated the Clean Water Act, EPA is proposing a change to its current practice regarding the facility specific information it collects from states and posts to its ECHO Web site for these facilities (unpermitted CAFOs and AFOs that state inspectors found were not discharging and do not require an NPDES permit). EPA is proposing to mask all facility identifying information for this subset of facilities and only post the information submitted by states on the total number of inspections of these facilities by state.

EPA is proposing to make this change a year after the effective date of the final rule. EPA anticipates it will need a year after the final rule to coordinate with states on identifying the exact set of CAFOs and AFOs currently in EPA's data systems that qualify for this proposed facility specific information redaction and the necessary data management rules for future state inspections of CAFOs and AFOs. This proposed change addresses the concerns from agricultural stakeholders about posting facility specific information for CAFOs that are not discharging and not required to have NPDES permits. EPA seeks comment on this proposed change and the proposed timing.

The following is an example of how EPA could mask facility name and location (address and latitude and longitude) as well as facility contact information (contact name and phone number) for its ECHO Web site. [Note: Each unpermitted CAFO and AFO that does not have a Clean Water Act violation as determined by the authorized state NPDES program or EPA would have a unique number as shown below in Facility #2.]

Facility #1—unmasked information	Facility #2—masked information
Show-Me State Animal Farm, Location: 11300 Ozark Lane, Perryville, Missouri 63775, County: Perry, Lat.: 37.836084, Long: −89.738644, Contact: Grant Wood, Phone: 999–867–5309, Inspection(s): 3/14/2010 (no violation identified); 6/22/2014 (discharging without an NPDES permit).	Unpermitted CAFO/AFO–0000001, Location: Missouri, County: Redacted from Web site, Lat./Long.: Redacted from Website, Contact: Redacted from Web site, Phone: Redacted from Website, Inspection(s): 2/17/2009 (no violation identified); 5/25/2013 (no violation identified).

The above table is provided for illustration only. In this hypothetical example, the unpermitted CAFO shown in the column labeled ''Facility #1—Unmasked Information'' would *not* have its facility and contact information displayed on EPA's Web site until the weekly refresh of ECHO data from ICIS–NPDES after 22 June 2014, which is the date the state or EPA Region identified that the facility had a Clean Water Act violation (*i.e.,* discharging without an NPDES permit) and entered these data into ICIS–NPDES. If an unpermitted CAFO does not have a Clean Water Act violation as determined by the authorized state NPDES program or EPA, then the facility and contact information would not be displayed on EPA's ECHO Web site (see the column labeled ''Facility #2—Masked Information'' in the above table).

EPA solicits comment on this approach. Additionally, under existing EPA regulations at 40 CFR part 2, subpart B, a facility, including any CAFO or AFO, may make a claim of confidentiality for information it must submit to EPA or to the authorized State. These claims will be processed and evaluated under federal or State regulations, respectively.

Agricultural stakeholders also commented that electronic reporting of NPDES program data may provide a disincentive to seek NPDES permit

[6] For example, EPA electronically collects Pre-manufacture Notices (PMNs) from chemical manufacturers through EPA's CDX system. These chemical manufacturers can claim these PMNs as CBI. See DCN 0116.

coverage in order to keep information related to the facility and facility contact out of EPA's databases. EPA has a statutory duty to implement a permitting program for CAFOs that discharge. This proposed rule does not change the requirement that CAFOs discharging pollutants into waters of the United States are subject to NPDES regulation.

Finally, in response to comments received, EPA is soliciting comment on a few changes to CAFO data elements in Appendix A to Part 127 (see DCN 0108). EPA believes that these edits, generated from comments by states, make the revised Appendix A more clear and implementable (see DCN 0128 through 0142).

D. Stormwater Sector

EPA received a number of comments on how electronic reporting will be implemented for NPDES-regulated entities that manage stormwater. The following section describes these comments.

1. Municipal Separate Storm Sewer Systems (MS4s)

Polluted stormwater runoff is commonly transported through Municipal Separate Storm Sewer Systems (MS4s), from which it is often discharged untreated into local waterbodies. To prevent harmful pollutants from being washed or dumped into an MS4, regulated entities (*e.g.,* municipalities) must obtain a NPDES permit and develop a stormwater management program. Under the proposed rule, MS4 regulated entities must electronically submit certain MS4 data. These data include: (1) Notices of intent (NOIs) for coverage under a NPDES general permit; and (2) MS4 program reports.

NPDES general permits are most often used by NPDES permitting authorities for Phase II MS4s (*i.e.,* smaller MS4s for which federal regulations were issued in 1999). The MS4-specific data elements related to NOI submissions are identified in Appendix A to 40 CFR part 127 at pp. 46093–46094 of the proposed rule. These MS4-specific data elements are in addition to basic facility and permit data that are also required to be submitted electronically, as identified in Appendix A to 40 CFR part 127 at pp. 46084–46088 of the proposed rule. In a separate data submission, the authorized NPDES program will also share MS4 information (*e.g.,* basic facility, permit, and MS4-specific information) from individual NPDES permit applications with EPA.

EPA also proposed a requirement that MS4-regulated entities electronically submit their MS4 program reports, which is an existing compliance monitoring reporting requirement [see 40 CFR 122. 42(c) and 40 CFR 122.34(g)(3)]. The required MS4-specific data elements from the MS4 program reports are identified in Appendix A to 40 CFR part 127 at pp. 46107–46108 of the proposed rule.

During the public comment period for the proposed rule, several commenters, particularly from local governments, provided EPA with MS4-related comments. Many of these commenters expressed concern about how EPA would implement electronic reporting for MS4 regulated entities. In particular, they noted that MS4 program reports are generally not uniform as each MS4 program implements its program differently. These commenters asked EPA to clarify its plans to standardize and electronically collect these data. EPA intends to use a combination of drop-down lists and text fields in its electronic reporting systems to effectively characterize the activities of the MS4 facilities for electronic reporting of NOIs and program reports. An example of this flexibility can be seen in EPA's NOI form for Phase II MS4 regulated entities in Region 1 (see DCN 0110). EPA recognizes that requirements will vary from one state to another; therefore, the electronic reporting systems developed by EPA or by other parties will need to be adaptable to reflect the additional information that particular states may seek in addition to the data described in Appendix A to 40 CFR part 127.

Some commenters indicated that it would be helpful if the information provided in electronic NOIs could be used to ''auto-fill'' or pre-populate data submitted with MS4 program reports. EPA is interested in making electronic reporting as easy as possible and will review this suggestion as part of the development of its NPDES eReporting Tool (NeT).

Several commenters also indicated that EPA should adjust Appendix A to 40 CFR part 127 to better reflect the different requirements and terminology utilized for Phase I MS4s (*i.e.,* those large and medium MS4s for which federal regulations were issued in 1990) and Phase II MS4s. EPA solicits comment on potential specific changes to Appendix A related to MS4s (see DCN 0108).

2. Industrial and Construction Stormwater Electronic Reporting

Stormwater runoff from construction and industrial activities can have a significant impact on water quality. As stormwater flows over a construction or industrial site, it can pick up pollutants like sediment, debris, and chemicals and transport these to a nearby storm sewer system or directly to a river, lake, or coastal water. The proposed rule requires construction operators and industrial facilities seeking coverage by an NPDES permit or a waiver from having to have NPDES permit coverage to electronically submit data.

In the preamble to the proposed rule (pp. 46025–46027) and in the proposed regulatory text [40 CFR 127.11(b)], EPA stated that operators of regulated construction sites and industrial facilities would be required to electronically submit NOIs for coverage under a NPDES general permit. Under the proposed rule authorized NPDES programs would also electronically process data from paper NPDES individual permit applications submitted by construction operators (see Appendix A). In total, this data includes certain categories of industrial activities and large construction sites regulated by the Phase I stormwater regulations promulgated in 1990 and small construction sites identified in the Phase II stormwater regulations promulgated in 1999. These regulated entities may already be required by their permits to electronically submit DMRs. In a separate data submission, the authorized NPDES program would also share additional information (*e.g.,* basic facility, permit, and construction and industrial stormwater information) with EPA from individual NPDES permit applications and waiver or exclusion from NPDES permitting determinations.

During the public comment period, some commenters indicated that the universe of NPDES-regulated construction sites was large and changing often as sites were completed. These commenters had concerns about how electronic reporting would work for this large and changing universe of NPDES-regulated entities. In particular, some of these commenters noted the difficulty in getting construction operators to apply for and maintain electronic signatures for use with CROMERR electronic reporting systems. As an alternative to use of a CROMERR electronic reporting system one commenter suggested EPA allow NPDES programs the possibility of using automatic identification and data capture technology [*e.g.,* two dimensional barcodes such as Quick Response (QR) codes, optical character recognition]. For example, a potential user could complete an online form and then print out a paper copy of the form with a two-dimensional barcode or in a format that can be used by an optical character reader. The potential user

would then certify these data as correct by signing this paper print-out in ink. The use of this data capture technology could enable a NPDES-regulated entity to submit NPDES program data on paper with a ''wet-ink'' signature and have the NPDES program data structured to allow easy data importation into the state data system and subsequent sharing with EPA. This would mean that the state would need to procure and manage this automatic identification and data capture technology, maintain the paper submission with the NPDES program data and ''wet-ink'' signature, and train potential users; however, some states have suggested this option may be less burdensome than requiring all construction stormwater NPDES-regulated entities to obtain and maintain a digital signature.

Some commenters suggested that EPA adjust the minimum set of federal NPDES data (Appendix A to 40 CFR part 127) to better distinguish between construction stormwater and industrial stormwater data elements as well as required data for individual application versus NOIs for coverage under a general permit. EPA solicits comments on these potential changes to Appendix A (see DCN 0108).

E. Economic Analysis

EPA received numerous comments related to its economic analysis of the incremental costs associated with the proposed rule. Commenters include state environmental agencies, municipalities, private industry, and trade groups and associations. The majority of the comments focused on rule implementation costs, data entry burden, dual reporting requirements, benefits of the rule, and impacts on small entities.

Commenters expressed concern that the economic analysis may not accurately reflect the financial impact on states because it excludes or underestimates costs for information technology (IT) system development and upgrades; annual IT maintenance and operation (*e.g.,* a hotline for NPDES-regulated entities; password resets; system maintenance); outreach and training for NPDES-regulated entities; training of program staff; and revisions to statutes or regulations to implement the proposed rule.

A number of commenters also suggested that that the Economic Analysis underestimated the costs to NPDES-regulated entities. For example, a number of larger companies, municipalities, and sanitation districts indicate that they would need to upgrade their data management systems to be compatible with the state's or EPA's new electronic system. They also expressed concern that the analysis underestimated costs to NPDES-regulated entities operating in multiple states, because they will need to generate customized reports related to permit conditions and state formatting requirements.

Small entities with NPDES permits such as small municipalities, CAFOs, and construction firms stated that the analysis did not take into account that some NPDES-regulated entities may need to buy a computer and obtain Internet access or travel to a site (*e.g.,* local library) with public access to computers in order to electronically enter and submit the required data. EPA notes that some of these facilities may be eligible for temporary waivers. Some commenters also noted that electronic data entry could be more difficult and time-consuming than writing data on paper, especially for entities that do not have extensive computer experience. Commenters indicated that attending trainings for the electronic systems could be a burden to small entities.

Some NPDES-regulated entities expressed concern that they could be designing their internal data management systems and procedures for electronic reporting directly to EPA and then potentially redesigning them for a different state system at a later time if the Initial Recipient changes.

Some commenters also questioned the benefits associated with the proposed rule. They argued that the reason that most states have not expanded electronic reporting to NOIs and program reports is because electronic reporting on seldom-reported documents (such as once a year reporting or once every five year No Exposure Certifications) or simple but very frequently received documents (such as Notices of Termination for construction stormwater general permits) will require more ad-hoc time and staff than accepting such documents via FAX, as PDFs via email, or as a hard copy. Some commenters also disagreed with EPA's analysis that the rule will result in improvements in water quality and increases in permittee compliance due to better awareness of compliance status and public scrutiny.

EPA received few data from commenters that can be used to update its economic analysis. EPA solicits additional data and information to inform the economic analysis supporting this rule (see EPA–HQ–OECA–2009–0274–0135). For example, EPA solicits data on the savings due to the more efficient form preparation and processing (including postage savings) as well as savings related to improved data quality as electronic reporting tools will include the ability to check for certain types of errors.

EPA received a number of comments regarding the proposed rule's potential Federalism implications, expressing concern that the proposal could infringe upon the lead role of authorized states, tribes, and territories. EPA wants to clarify that it does not intend to change or infringe upon the lead role of authorized states, tribes, and territories. The purpose of the proposed rule is to shift the collection and management of information from NPDES forms and reports from a paper-based system to an electronic-based system. The proposed rule does not change the well-established relationship between EPA and authorized state, tribal, and territorial programs as these authorized programs will continue to be the lead in all aspects of the NPDES program including permitting, inspections, compliance determinations, and enforcement actions. Under the existing regulatory scheme, authorized states, tribes, territories are already required to collect the information covered by this rule from NPDES-regulated entities and make it available to EPA. The main focus of the proposed rule is to have that information submitted electronically, saving time and money for states as well as the regulated community. EPA notes that close coordination and discussion with states about the best way to move towards the shared goal of shifting to electronic reporting is very important and EPA has gone beyond just complying with the Presidential Executive Order that requires EPA to work collaboratively with states and local governments. Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' EPA and several authorized state NPDES programs are regularly holding discussions and technical exchanges on all aspects of the rulemaking (see DCN 0111) and these discussions have meaningfully informed several aspects of this supplemental notice. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and state and local governments, EPA specifically solicits comment on the proposed rule and this supplemental notice from state and local officials. EPA will continue to consult with state and local officials throughout the rule development process to ensure they

have meaningful and timely opportunities for input.

F. Waivers

In the preamble to the proposed rule, EPA introduced the concept of temporary waivers from electronic reporting of NPDES information. As described in the proposed rule at 40 CFR 127.15, these temporary waivers would be made available at the discretion of the authorized NPDES program (and subject to EPA review) in situations where regulated facilities lacked sufficient broadband availability. The process for granting such temporary waivers from electronic reporting is described in the proposed regulation at 40 CFR 127.24. Authorized NPDES programs would be required to enter the hard-copy NPDES information submitted by facilities with waivers into the state or federal NPDES data system and share it with EPA. Under the proposal, temporary waivers would be available for one year at a time. EPA requested comment on the need for such temporary waivers, possible options for such waivers, and on the possibility of temporary waivers for religious reasons.

During the public comment period for the proposed rule, EPA received several comments on temporary waivers. The majority of the comments on this topic supported the overall concept of temporary waivers from NPDES electronic reporting; three commenters disagreed. Commenters suggested that EPA should make permanent waivers for NPDES-regulated entities located in religious communities (*e.g.,* Amish, Mennonite, and Hutterite). Other comments indicated support for making temporary waivers automatic in certain locations (*e.g.,* areas where less than 10 percent of the population has sufficient broadband availability). Commenters expressed support for waivers that would have a longer duration than the one-year renewable timeframe identified in the proposed rule. Several commenters suggested that waivers should also be made available for certain circumstances beyond broadband availability issues, such as undue burden or cost. States also requested that they be provided with more flexibility in providing waivers from electronic reporting. A few commenters also suggested that EPA make the determinations of temporary waiver eligibility rather than the states, even if the state has authorization to implement the NPDES program. As described in Section IV, EPA solicits comment on temporary waivers and permanent waivers for NPDES-regulated entities located in religious communities.

G. Miscellaneous Issues

This section describes other issues raised by commenters.

1. Electronic Reporting for the Pesticides General Permit and Vessels General Permit

Several commenters had questions regarding the application of the proposed rule to regulated entities subject to EPA's Pesticides General Permit and Vessels General Permit. EPA provides NPDES permit coverage for pesticide applicators where EPA is the permitting authority and vessel operators nationwide. These permits predate the proposed NPDES Electronic Reporting Rule; however, EPA has developed an electronic reporting system for these regulated entities to submit Notices of Intent (NOIs) for coverage under these general permits. EPA currently allows operators to request a waiver from electronic reporting based on an undue burden or expense associated with electronic reporting (see DCN 0112). There are no additional costs to EPA or the operators regulated by EPA's pesticide applicators and vessels general permits with implementation of the proposed rule as nearly all of these regulated entities are already using EPA's electronic reporting system. EPA will incorporate data on pesticide applicators regulated by state permits into the economic analysis.

EPA is not proposing to exempt these two permits from the NPDES Electronic Reporting Rule. In particular, EPA's General Permit regulations (40 CFR 122.28) apply to all general permits and EPA's proposed revisions to this regulatory language that implement electronic reporting do not exclude pesticide applicators or vessel operators (or any other sector or general permit). EPA will require electronic reporting of general permit reports (*i.e.,* NOIs, NOTs, LEWs, and NECs) and DMRs (if required by the NPDES permit) when it re-issues these permits after the effective date of the final rule. EPA intends to clarify this in the final rule and supporting documentation.

2. Modification of Data Elements in Appendix A

In response to public comments on the proposed rule, EPA reviewed the minimum set of federal NPDES data (Appendix A to 40 CFR part 127) and is seeking comment on potential changes to some of these data elements (see DCN 0108). Additionally, EPA is seeking comment on including two data elements that support the Clean Watersheds Needs Survey, which is conducted by EPA under authority of Sections 205(a) and 516 of the Clean Water Act. These changes would reduce burden on states by eliminating most of the need for EPA to collect these two data elements from states as part of its quadrennial survey. These two POTW data elements are: (1) POTW Wastewater Treatment Technology Level Description [The highest level of treatment (*e.g.,* primary equivalent to secondary, secondary, advanced, other) that the POTW provides at each outfall]; and (2) POTW Wastewater Treatment Technology Unit Operations [The treatment technology unit process information at each outfall for POTWs greater than 10 MGD]. Example wastewater treatment technology level descriptions and unit operations are provided in the docket (see DCN 0113).

3. Biosolids Annual Report

Several EPA Regions are using the DMR form to collect data for the Biosolids Annual Report as required by EPA regulations.[7] These regulations require that all Publicly Owned Treatment Works (POTWs) servicing a population greater than 10,000, having a design flow rate greater than one million gallons per day, or designated as Class I facilities submit an annual report to the permitting authority every year on February 19th. In particular, EPA Region 6 is using the NetDMR electronic reporting system to collect data for the Biosolids Annual Report from facilities in Region 6 states (see DCN 0114 and 0115). EPA solicits comment on the practicality of using the DMR form to collect data for the Biosolids Annual Report. EPA notes that using the DMR form may be difficult to capture specific information related to pathogen reduction methods, vector attraction reduction methods, cumulative and annual loading rates, incineration related data, and site restrictions. EPA notes that the use of the DMR form to report Biosolid Annual Report data, while more efficient, may reduce the ability of the authorized NPDES program to determine facility-level compliance. EPA also solicits comment on allowing POTWs to use state eDMR systems to submit their Biosolids Annual Report when the state is not authorized for the biosolids program.[8]

EPA also solicits comment on changing the deadline for submission of these Biosolids Annual Reports from Phase 2 (two years after the effective date of the final rule) to Phase 1 (one

[7] See ''Standards for the Use or Disposal of Sewage Sludge,'' 40 CFR part 503.

[8] EPA has authorized eight states to run the Federal biosolids program (40 CFR part 503). These eight states are Arizona, Michigan, Oklahoma, Oregon, South Dakota, Texas, Utah, and Wisconsin.

year after the effective date of the final rule). EPA notes that only eight states are authorized to run the Federal Biosolids Program (40 CFR part 503). This means that EPA implements the biosolids program and collects these annual reports for 42 states as well as tribes and territories.

In addition, EPA Region 7 (Kansas City, KS) is the EPA National Biosolids Center of Excellence and this center is dedicated to creating efficiencies in the Federal Biosolids Program. EPA's National Biosolids Center coordinates all assistance to states and NPDES regulated entities on the Federal Biosolids Program and collects and reviews Biosolids Annual Reports for all facilities in the 42 states as well as tribes and territories where EPA implements the NPDES program for biosolids. This EPA office is capable of standardizing the Annual Biosolids Report for those 42 states, tribes, and territories, and providing individual help for each of the eight authorized states in order to resolve any outstanding implementation issues (*e.g.,* State Readiness Criteria) within the first year of implementation of the rule. EPA would like to realize the many benefits of electronic reporting for the Annual Biosolids Report as soon as possible and solicits comment on changing the deadline for submission of these Biosolids Annual Reports from Phase 2 to Phase 1.

IV. Matters for Which Comments Are Sought

The following sections identify specific issues on which EPA invites comment. Please note that there is no need to re-submit comments previously submitted to EPA's docket for this rulemaking. You may find the following suggestions helpful when preparing your comments to EPA on the proposed rule and this notice:

- To ensure proper receipt by EPA, identify the appropriate docket identification number (found in the **ADDRESSES** section of this **Federal Register** notice) in the subject line on the first page of your comments or response.
- To help ensure that your submission is routed correctly, on the first page of your submission, provide the name of the proposed rule; date of the **Federal Register** notice; and the **Federal Register** citation (*e.g.,* ____ [volume number] FR ____ [page number]) related to your comments or response.
- Clearly identify those sections of the preamble or the proposed rule on which you are commenting.
- Explain why you agree or disagree, and explain your views as clearly as possible.
- Describe clearly any assumptions that you used as a basis for your comments.
- Provide any technical information and/or data that you used to support your views.
- If you provide any estimate of potential economic burdens or costs, please carefully consider the information provided in the preamble to the proposed rule, particularly in Sections VII (Non-Monetary Benefits and Economic Analysis), VIII.A (Regulatory Planning and Review), VIII.C (Regulatory Flexibility Act), and IV.D (Data Considerations), and provide detailed explanations of how you arrived at your estimate.
- Provide specific examples to illustrate your comments or concerns.
- Clearly identify your preferences and, if applicable, offer feasible alternatives that will effectively meet the same goals.

Submit your comments as directed in the **ADDRESSES** section of this **Federal Register** notice before the comment period deadline identified in the **DATES** section of this notice.

A. Implementation Plan

1. EPA solicits comment from the states on making the Initial Recipient determination in Section 127.27(a) an 'opt-out' process for an authorized state, tribe, or territory NPDES programs. Under this process, an authorized NPDES program would need to notify EPA within 120 days of the effective date of the final rule if it wishes EPA to be the Initial Recipient for a particular data group. If EPA receives no such notification, EPA would designate the state, tribe, or territorial NPDES program as the Initial Recipient.

2. EPA solicits comment on additional means for providing notice to NPDES regulated entities on the Initial Recipient status.

3. In order to provide a clearer distinction between the Initial Recipient and State Readiness Criteria terms, EPA solicits comment on eliminating the third factor in the State Readiness Criteria (*i.e.,* Initial Recipient Status).

4. EPA solicits comment on different options for using a phased approach or longer interval before applying participation rate as part of the State Readiness Criteria. For example, EPA could require increasing participation rates over a longer implementation period (*e.g.,* 30 percent participation rate for Year 1, 60 percent participation rate for Year 2, and 90 percent participation rate for Year 3).

5. EPA solicits comment on the concept of using EPA's CWA authority through use of an ICR to require NPDES-regulated entities to electronically submit their NPDES program data to their authorized state, tribe, or territory as a ''fill in the gaps'' measure where the authorized NPDES program has a CROMERR-approved electronic tool. The proposed rule had NPDES-regulated entities reporting these data to EPA. EPA would retain the ability to assess and pursue enforcement actions on NPDES-regulated entities that fail to comply with the data submission requirements.

6. EPA solicits comment on extending or adding additional phasing to the implementation period, linking implementation of electronic reporting to the NPDES permit cycle for entities with NPDES permits, or allowing states to extend their implementation of electronic reporting to a specific date following EPA approval of their individual implementation plan. These implementation plans would need to be approved by the authorized NPDES Director (as defined in 40 CFR 122.2).

7. EPA solicits comment on the option to calculate for each authorized NPDES program one DMR electronic submission participant rate for individually permitted facilities and another DMR electronic submission participant rate for general permit covered facilities.

8. EPA solicits comments on practical ways to streamline the implementation of the approval process for CROMERR within the parameters of the existing CROMERR regulation.

9. EPA solicits comment on the option of EPA using its CWA authority through use of an ICR to require facilities operating under backlogged permits to electronically submit their NPDES program data.

B. Stormwater Sector

1. EPA solicits comment on its proposed approach to use a combination of drop-down lists and text fields in its electronic reporting systems to effectively characterize the activities of the MS4 facilities for electronic reporting of NOIs and program reports.

2. EPA solicits comment on providing flexibility in the final rule for the construction stormwater program that would allow authorized NPDES programs the possibility of using automatic identification and data capture technology (*e.g.,* two dimensional barcodes, optical character recognition) instead of requiring construction site operators to secure and maintain electronic signature

credentials for use with CROMERR compliant electronic reporting systems.

3. EPA also solicits comment on changes to stormwater data elements in Appendix A (see DCN 0108).

C. Concentrated Animal Feeding Operations (CAFO) Sector

1. EPA solicits comment on the approach of removing facility specific information from EPA's ECHO Web page about non-permitted CAFO/AFOs that state inspectors found were not discharging and do not require an NPDES permit. As discussed in this notice, EPA is proposing to mask facility specific information on these unpermitted CAFO/AFOs and only show the total number of these masked facilities by state. EPA plans to enhance its data system (ICIS–NPDES) to provide states and Regions with the necessary capability to identify these non-permitted CAFO/AFOs that do not require an NPDES permit. In particular, after these enhancements States and Regions will need to enter or verify the following data into ICIS–NPDES for each non-permitted CAFO/AFO that does not require an NPDES permit: (1) Unpermitted CAFO/AFO has an ''Unpermitted ID'' with no associated ''NPDES Permit ID;'' (2) unpermitted CAFO/AFO has a ''CAFO Permit Component;'' and (3) unpermitted CAFO/AFO has no CWA NPDES violations. If these three conditions are met EPA will remove facility specific information for these facilities from EPA's ECHO Web page one year after the effective date of the final rule. EPA solicits comment on the timing of this proposed change.

2. As previously discussed in Section III.C, agricultural stakeholders focused their comments on the public availability of Appendix A data related to CAFOs. EPA emphasizes that this rule would not require any information to be disclosed that is not already available to EPA and the public pursuant to the Clean Water Act.

3. EPA is soliciting comment on a few changes to CAFO data elements in Appendix A to Part 127 (see DCN 0108). EPA believes that these edits, generated from comments by states, make the revised Appendix A more clear and implementable (see DCN 0128 through 0142).

D. Economic Analysis

1. EPA solicits comment on what NPDES program information technology upgrades might be necessary for regulatory authorities or NPDES-regulated entities. For example, EPA seeks information on the labor hours and capital equipment and/or software needed to upgrade or expand state batch system databases to store all Appendix A data. For labor hour estimates, please provide the labor category for the hours needed. Please also provide information on the number of Appendix A data elements for which the upgrade/expansion is needed.

2. EPA solicits comment on the expected costs for CROMERR implementation as it specifically relates to the proposed NPDES Electronic Reporting Rule. For example, please provide estimates of burden (including labor category) and costs for using EPA's electronic reporting systems.

3. EPA solicits comment on the expected costs for eNOI and eProgram Report training. For example, please provide the amount of training (in labor hours) that NPDES-regulated entities and states would require in the use of electronic systems for NOIs and program reports, including the labor categories (*e.g.,* managerial, technical, clerk, etc.). EPA will be training states that elect to use EPA's electronic reporting systems on how to use these tools and how to train potential users. EPA will work with states on the training needs of potential users and conduct some training sessions at the request of the states. States will also be responsible for conducting regular training sessions for NPDES-regulated entities on how to use EPA's electronic reporting systems.[9]

4. EPA solicits comment on costs related to computer and Internet access for NPDES-regulated entities. For example, EPA solicits comment and information on the number or percent of NPDES-regulated entities that do not currently have readily available access to a computer and/or the Internet. Please also provide the estimated cost of a computer and/or Internet access and the labor hours and labor categories as well as any travel expenses related to offsite computer and Internet access (*e.g.,* local public library).

5. EPA solicits comment on costs related the use of existing electronic systems. For example, EPA asks authorized NPDES programs to provide information on the utilization of existing electronic systems in terms of the percent of major and minor permittees (by individual and general permit covered facilities) and other NPDES-regulated entities actively reporting to DMR, NOIs, and/or program report systems.

6. EPA solicits comments on the difference in labor hours associated with the current regulatory requirement for states to produce an annual noncompliance report (ANCR) versus the labor hours that would be associated with a state's review of non-major noncompliance information in the proposed quarterly NPDES noncompliance report (NNCR) generated by EPA.

E. Waivers

1. EPA solicits comment on whether waivers from NPDES electronic reporting should be automatic for counties where only a small fraction of the population (*e.g.,* less than 10 percent) has sufficient broadband availability.

2. EPA solicits comment on the appropriate effective timeframe for these ''automatic'' waivers. Should there be a review period for these ''automatic'' waivers?

3. EPA solicits comment on whether temporary waivers should extend for the life of the NPDES permit or another timeframe.

4. EPA solicits comment on whether EPA should allow authorized NPDES programs to grant a temporary waiver based on the NPDES-regulated entity's lack of technical expertise and what criteria, if any, the authorized program should use in making these decisions.

5. EPA solicits comment on whether it should make available in the final rule permanent waivers for NPDES-regulated entities located in religious communities where electronic reporting would not be consistent with the community's religious beliefs (*e.g.,* Amish, Mennonite, and Hutterite).

F. Miscellaneous Issues

1. EPA is soliciting comment on how to improve public accessibility and usability of the data. EPA notes that this proposed rule does not change the Agency's public disclosure regulations (40 CFR 2).

2. EPA reviewed the minimum set of federal NPDES data (Appendix A to 40 CFR part 127) and is seeking comment on potential changes to some of these data elements (see DCN 0108).

3. EPA solicits comment on the practicality of using the DMR form to collect data for the Biosolids Annual Report. EPA also solicits comment on allowing POTWs to use state eDMR systems to submit their Biosolids Annual Report when the state is not authorized for the biosolids program.

4. EPA also solicits comment on changing the deadline for submission of these Biosolids Annual Reports from Phase 2 (two years after the effective date of the final rule) to Phase 1 (one

[9] See the economic analysis for the proposed rule for more information on these training sessions (EPA–HQ–OECA–2009–0274–0135).

year after the effective date of the final rule).

V. Outreach

Section VI of the proposed rule details EPA extensive outreach efforts prior to the proposed rule. EPA continued this outreach during the public comment period on the proposed rule (DCN 0111). In particular, EPA held over 30 webinars and meetings with over 1,200 people to discuss the proposed rule.

Upon publication of this notice, EPA will provide a new comment period and will conduct additional stakeholders meetings to further discuss and refine particular aspects of the rule prior to promulgation. Outreach to stakeholders will continue to be supported through the NPDES Electronic Reporting Rule Web site; however, the Web site may be expanded to include more robust rule schedules as the rule nears promulgation, as well as additional rule documentation that may or may not be included as part of the formal docket library. Stakeholders that wish to hold a meeting with EPA should send an email to Messrs. Hudock or Johnston (see **FOR FURTHER INFORMATION CONTACT** section).

Finally, EPA would also continue to provide technical assistance and support to states, tribes, and territories during the transition to electronic reporting. Outreach from EPA to the states, tribes, and territories may be very useful in the identification of specific needs and the development of such assistance, support, and funding. EPA also solicits comment and suggestions on how to reach and inform the broad range of facilities affected by this proposed rulemaking.

VI. Executive Orders 12866 and 13563

Under Executive Order (EO) 12866 [58 FR 51735 (October 4, 1993)] this action is a ''significant regulatory action.'' Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 and any changes made in response to OMB recommendations have been documented in the docket for this action.

List of Subjects

40 CFR Part 122

Administrative practice and procedure, Confidential business information, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 123

Administrative practice and procedure, Confidential business information, Hazardous substances, Indians—lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 127

Administrative practice and procedure, Electronic reporting requirements, Water pollution control.

40 CFR Part 403

Administrative practice and procedure, Compliance monitoring, Enforcement program and activities, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 501

Administrative practice and procedure, Indians—lands, Intergovernmental relations, Penalties, requirements, Sewage disposal.

40 CFR Part 503

Reporting and recordkeeping requirements, Sewage disposal.

Dated: November 18, 2014.

Cynthia Giles,

Assistant Administrator, Office of Enforcement and Compliance Assurance.

[FR Doc. 2014–27918 Filed 11–28–14; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 410, 418, 440, 484, 485 and 488

[CMS–3819–N]

Medicare and Medicaid Programs; Conditions of Participation for Home Health Agencies; Extension of Comment Period

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of extension of comment period.

SUMMARY: This notice extends the comment period for the October 9, 2014 proposed rule entitled ''Conditions of Participation for Home Health Agencies'' (79 FR 61164). The comment period for the proposed rule, which would have ended on December 8, 2014, is extended for 30 days.

DATES: The comment period is extended to 5 p.m. Eastern Standard Time on January 7, 2015.

ADDRESSES: In commenting, please refer to file code CMS–3819–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3819–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3819–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any

personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

FOR FURTHER INFORMATION CONTACT: Danielle Shearer (410) 786–6617. Jacqueline Leach (410) 786–4282. Maria Hammel (410) 786–1775.

SUPPLEMENTARY INFORMATION: On October 9, 2014, we published a proposed rule in the **Federal Register** (79 FR 61164) entitled, ''Conditions of Participation for Home Health Agencies'' that would revise the health and safety requirements that home health agencies (HHAs) must meet in order to participate in the Medicare and Medicaid programs. Specifically, the proposed requirements would focus on the care delivered to patients by home health agencies, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements. In addition, we proposed a set of fundamental requirements for HHA services that would encompass patient rights, comprehensive patient assessment, and patient care planning and coordination by an interdisciplinary team. Overarching these requirements would be a quality assessment and performance improvement program that would build on the philosophy that a provider's own quality management system is key to improved patient care performance. The objective would be to achieve a balanced regulatory approach by ensuring that a HHA furnished health care that met essential health and quality standards, while ensuring that it monitored and improved its own performance. These changes are an integral part of our overall effort to achieve broad-based, measurable improvements in the quality of care furnished through the Medicare and Medicaid programs, while at the same time eliminating unnecessary procedural burdens on providers.

We have received inquiries from state-based and national industry organizations regarding the 60 day turn-around time to submit comments regarding this proposed rule. The organizations stated that they needed additional time to respond to the rule due to the complex nature of the proposed revisions. Because of the scope of the proposed rule, and since we have specifically requested the public's comments on various aspect of the rule in an attempt to benefit from the vast experiences of the HHA provider and patient communities, we believe that it is important to allow ample time for all sections of the public to comment on this proposed rule. Therefore, we have decided to extend the comment period for an additional 30 days. This document announces the extension of the public comment period to January 7, 2015.

Dated: November 24, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–28266 Filed 11–28–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 401

[USCG–2014–0481; 1625–AC22]

Great Lakes Pilotage Rates—2015 Annual Review and Adjustment—Extension of Comment Period

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard is extending the comment period for the notice of proposed rulemaking (NPRM) entitled ''Great Lakes Pilotage Rates—2015 Annual Review and Adjustment,'' published on September 4, 2014, for 30 days. We have decided to extend the comment period as we have received new financial data that could affect the discretion provided by Step 7 of the Appendix A methodology and the final rate.

DATES: Comments and related material must either be submitted to our online docket via *http://www.regulations.gov* on or before December 31, 2014 or reach the Docket Management Facility by that date.

ADDRESSES: You may submit comments identified by docket number USCG–2014–0481 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Mr. Todd Haviland, Director, Great Lakes Pilotage, Commandant (CG–WWM–2), Coast Guard; telephone 202–372–2037, email *Todd.A.Haviland@uscg.mil,* or fax 202–372–1914. If you have questions on viewing or submitting material to the docket, call Ms. Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

A. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2014–0481), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. We recommend that you include your name and a mailing address, an email address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and insert ''USCG–2014–0481'' in the ''Search''

box. Click on ''Submit a Comment'' in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this notice of proposed rulemaking (NPRM) based on your comments.

B. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* and insert ''USCG–2014–0481'' in the ''Search'' box. Click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. If you do not have access to the Internet, you may view the docket online by visiting 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. We have an agreement with the Department of Transportation to use the Docket Management Facility.

C. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

II. Regulatory History and Information

The Coast Guard published an NPRM entitled ''Great Lakes Pilotage Rates—2015 Annual Review and Adjustment,'' on September 4, 2014, (79 FR 52602) proposing rate adjustments for pilotage services on the Great Lakes, last amended in March 2014. The proposed adjustments would establish new base rates made in accordance with a full ratemaking procedure. Additionally, the Coast Guard proposed to exercise the discretion provided by Step 7 of the Appendix A methodology to result in an upward adjustment to match the rate increase of the Canadian Great Lakes Pilotage Authority. The NPRM also proposed temporary surcharges to accelerate recoupment of necessary and reasonable training costs for the pilot associations. All comments on this NPRM were originally due by November 3, 2014.

III. Background and Purpose

On November 14, 2014, we received the final reports of the revenue audits conducted by CohnReznick, LLP for the three pilotage districts. Performance of these audits was unanimously recommended by the Great Lakes Pilotage Advisory Committee to the Coast Guard at the most recent committee meeting on July 23–24, 2014, in Washington, DC. The data found by the revenue audits are important to analyzing the proposed rule as the findings may alter the final rate. We believe that the data provided in the revenue audits are ''other supportable circumstances'' that may alter the rate through the discretion provided by Step 7 of the ratemaking methodology. As these revenue audits were received after the comment period closed, we wish to give commenter's the opportunity to review these revenue audits, which can be found in the docket, and make comments on the revenue audits.

V. Authority

This notice is issued under authority of 5 U.S.C. 552(a).

Dated: November 25, 2014.

Scott J. Smith,

Captain, U.S. Coast Guard, Acting Director of Marine Transportation Systems, U.S. Coast Guard.

[FR Doc. 2014–28272 Filed 11–28–14; 8:45 am]

BILLING CODE 9110–04–P

Notices

Federal Register
Vol. 79, No. 230
Monday, December 1, 2014

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

Office of the Chief Financial Officer

Notice of Request for Approval of a New Information Collection

AGENCY: Office of the Chief Financial Officer, Department of Agriculture.

ACTION: Notice and request for comments.

SUMMARY: This notice announces the intention of the Office of the Chief Financial Officer to request approval for a new information collection for suspension and debarment and drug-free workplace certifications.

DATES: Comments on this notice must be received by January 30, 2015 to be assured of consideration.

ADDRESSES: Comments may be submitted by either/one of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Postal Mail/Commercial Delivery:* Send to Director, Transparency and Accountability Reporting Division, Office of the Chief Financial Officer, Room 3022–S, Stop Code 9011, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250.

All comments received will be available for public inspection and posted without change, including any personal information, to *http://regulations.gov.* or during regular business hours at the same address.

FOR FURTHER INFORMATION CONTACT: Tyson P. Whitney, Director, Transparency and Accountability Reporting Division, Office of the Chief Financial Officer, Room 3027–S, Stop Code 9011, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250; (202) 720–8978; *tyson.whitney@cfo.usda.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the intention of the Office of the Chief Financial Officer to request approval for a new information collection for suspension and debarment and drug-free workplace certifications.

Title: Suspension and Debarment and Drug-Free Workplace Certifications.

OMB Number: 0505–New.

Expiration Date of Approval: Three years from approval date.

Type of Request: New information collection.

Abstract: The information will be collected by USDA Federal financial assistance agencies as certifying information concerning applicant suitability in compliance with Federal Suspension and Debarment and Drug-Free Work Place regulations, as defined by 2 CFR parts 180, 417 and Pub. L. 100–690, Title V, Subtitle D: 41 U.S.C. 8101 *et seq.,* 2 CFR parts 182 and 421. Suspension and debarment is a discretionary or statutory administrative action taken by Federal agencies to protect the government by excluding persons and entities who are not presently responsible from participating in Federal programs or activities. Federal agencies are also prohibited from awarding financial assistance unless conditions are met that speak to recipient awareness of the unlawful manufacture, distribution, dispensation, possession, or use of a controlled substance while conducting any activity with the use of Federal financial assistance. The five forms that USDA will use with its financial assistance applications to collect the data include: (1) *AD–1047*—Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions; (2) *AD–1048*—Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions; (3) *AD–1049*—Certification Regarding Drug Free Workplace Requirements (Grants) Alternative 1 (For Grantees Other Than Individuals; (4) *AD 1050*—Certification Regarding Drug Free Workplace Requirements (Grants) Alternative 2 (For Grantees Who Are Individuals); and (5) *AD–1052*—Certification Regarding Drug Free Workplace Requirements-State and State Agencies).

Estimate of Burden: Public reporting burden for this total collection of information is estimated to average 0.25 hours per response per individual form. This burden is assumed for all of the forms in the aggregate.

Type of Respondents: Individuals or private entities; businesses or other for profit; not-for profit; Federal, state, local or tribal governments; institutions of higher education or other research organizations; foreign organizations.

Estimated Number of Respondents: 34,159.

Estimated Number of Responses: 68,318.

Estimated Number of Responses per Respondent: 2.

Estimated Total Annual Burden on Respondents: 17,080.

Form	Number of respondents	Number of responses per respondent	Number of responses	Average time to prepare (hrs)	Total annual burden on respondents (hrs)
AD–1047	10,441	2	20,883	0.25	5,221
AD–1048	10,186	2	20,372	0.25	5,093
AD–1049	6,156	2	12,311	0.25	3,078
AD–1050	3,059	2	6,118	0.25	1,529
AD–1052	4,317	2	8,635	0.25	2,159
Total	34,159	2	68,318	0.25	17,080

Comments from interested parties are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Jon M. Holladay,

Chief Financial Officer.

[FR Doc. 2014–28181 Filed 11–28–14; 8:45 am]

BILLING CODE 3410–KS–P

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket Number 141114970–4970–01]

2014 Company Organization Survey

AGENCY: Bureau of the Census, Commerce.

ACTION: Notice of determination.

SUMMARY: The Bureau of the Census (Census Bureau) publishes this notice to announce that it is conducting the 2014 Company Organization Survey. The survey's data are needed, in part, to update the multilocation companies in the Business Register. We have determined that annual data collected from this survey have significant application to the needs of the public and industry and are needed to aid the efficient performance of essential governmental functions. The data derived from this survey are not available from any other source.

ADDRESSES: The Census Bureau will furnish report forms to organizations included in the survey, and additional copies are available upon written request to the Director, U.S. Census Bureau, Washington, DC 20233–0101.

FOR FURTHER INFORMATION CONTACT: Anthony M. Caruso, Economy-Wide Statistics Division, U.S. Census Bureau, Room 6K153, Washington, DC 20233–6100 or by email at *Anthony.M.Caruso@census.gov.*

SUPPLEMENTARY INFORMATION: Sections 182, 224, and 225 of Title 13, United States Code (U.S.C.), authorize the Census Bureau to undertake surveys necessary to furnish current data on the subjects covered by the major censuses. Years that end in ''2'' and ''7'' are considered economic ''census years.'' All other years, other than the years when the economic censuses are conducted, are considered ''non-census'' years. In non-census years, companies report only on basic company affiliation and operations of establishments. In these non-census years, all multi-establishment companies with 500 or more employees report survey information. Also, groups of smaller companies that are divided into panels may be selected to report information for one of the non-census years. Smaller companies may be selected if an organizational change within the company is indicated or if they have been selected through probability sampling. The next economic census will be conducted for 2017.

This notice announces that the Census Bureau is conducting the 2014 Company Organization Survey. The survey is designed to collect information on the number of employees, payroll, geographic location, current operational status, and kind of business for each establishment of companies with more than one location. We have determined that annual data collected from this survey have significant application to the needs of the public and industry, and are needed to aid the efficient performance of essential governmental functions. The survey's data are needed, in part, to update the multilocation companies in the Business Register. The data collected in the Company Organization Survey will be within the general scope, type, and character of those that are covered in the economic censuses. Forms NC–99001 (for multi-establishment companies) and NC–99007 (for single-location companies) will be used to collect the desired data. The data derived from this survey are not available from any other source.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid Office of Management and Budget (OMB) control number. In accordance with the Paperwork Reduction Act, the OMB approved Forms NC–99001 and NC–99007 under OMB Control Number 0607–0444. We will furnish report forms to organizations included in the survey, and additional copies are available upon written request to the Director, U.S. Census Bureau, Washington, DC 20233–0101.

I have, therefore, directed that the 2014 Company Organization Survey be conducted for the purpose of collecting these data.

Dated: November 24, 2014.

John H. Thompson,

Director, Bureau of the Census.

[FR Doc. 2014–28264 Filed 11–28–14; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of National Advisory Council on Innovation and Entrepreneurship Meeting

AGENCY: Economic Development Administration, Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The National Advisory Council on Innovation and Entrepreneurship (NACIE) will hold an organizational meeting on Friday, December 5, 2014. This notice revises the notice previously published on November 18, 2014. The meeting will be held from 8:30 a.m.–11:15 a.m. Eastern Standard Time (EST) and will be open to the public. During this time, the following agenda topics will be covered: Remarks from Secretary Pritzker, Commerce Co-Chairs, newly-elected NACIE co-chairs, member introductions, and former NACIE experiences (Steve Case). The meeting will take place at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 4830, Washington, DC 20230.

DATES: December 5, 2014.

Time: 8:30 a.m.–11:15 a.m. EST.

ADDRESSES: U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 4830, Washington, DC 20230.

SUPPLEMENTARY INFORMATION: The Council was chartered on November 10, 2009 to advise the Secretary of Commerce on matters related to innovation and entrepreneurship in the United States. NACIE's overarching focus is recommending transformational policies to the Secretary that will help U.S. communities, businesses, and the workforce become more globally competitive. The Council will operate as an independent entity within the Office of Innovation and Entrepreneurship (OIE), which is housed within the U.S.

Commerce Department's Economic Development Administration. NACIE members are a diverse and dynamic group of successful entrepreneurs, innovators, and investors, as well as leaders from nonprofit organizations and academia.

The purpose of this organizational meeting is to discuss the Council's planned work initiatives in three focus areas: Workforce/talent, entrepreneurship, and innovation. The final agenda will be posted on the NACIE Web site at *http://www.eda.gov/oie/nacie/* prior to the meeting. Any member of the public may submit pertinent questions and comments concerning the Council's affairs at any time before or after the meeting. Comments may be submitted to the Office of Innovation and Entrepreneurship at the contact information below. Those unable to attend the meeting in person but wishing to listen to the proceedings can do so through a conference call line 1–888–790–3143, passcode: 8465571. Copies of the meeting minutes will be available by request within 90 days of the meeting date.

FOR FURTHER INFORMATION CONTACT: Julie Lenzer Kirk, Office of Innovation and Entrepreneurship, Room 70003, 1401 Constitution Avenue NW., Washington, DC 20230; email: *NACIE@doc.gov;* telephone: 202–482–8001; fax: 202–273–4781. Please reference ''NACIE December 5, 2014'' in the subject line of your correspondence.

Dated: November 24, 2014.

Julie Lenzer Kirk,

Director, Office of Innovation and Entrepreneurship.

[FR Doc. 2014–28200 Filed 11–28–14; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–428–840]

Lightweight Thermal Paper From Germany: Preliminary Results of Antidumping Duty Administrative Review; 2012–2013

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on lightweight thermal paper (LWTP) from Germany. The period of review (POR) is November 1, 2012, through October 31, 2013. The review covers one producer and exporter of the subject merchandise, Papierfabrik August Koehler SE (Koehler). We preliminarily determine that sales of subject merchandise by Koehler have not been made at prices below normal value. Interested parties are invited to comment on these preliminary results.

DATES: *Effective Date:* December 1, 2014.

FOR FURTHER INFORMATION CONTACT: David Goldberger, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC, 20230; telephone (202) 482–4136.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The merchandise covered by the order is lightweight thermal paper. The merchandise subject to the order is currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 3703.10.60, 4811.59.20, 4811.90.8000, 4811.90.8030, 4811.90.8040, 4811.90.8050, 4811.90.9000, 4811.90.9030, 4811.90.9035, 4811.90.9050, 4811.90.9080, 4811.90.9090, 4820.10.20, and 4823.40.00. Although the HTSUS numbers are provided for convenience and customs purposes, the written product description, available in the *Order,* remains dispositive.[1]

Methodology

The Department conducted this review in accordance with sections 751(a)(1)(B) and (2) of the Tariff Act of 1930, as amended (the Act). Export price and constructed export price are calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum, which is hereby adopted by this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Preliminary Results of the Review

As a result of this review, we preliminarily determine that a weighted-average dumping margin of 0.00 percent exists for Koehler for the period November 1, 2012, through October 31, 2013.

Disclosure and Public Comment

We will disclose the calculations performed to parties in this segment of the proceeding within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Interested parties may submit case briefs not later than 30 days after the date of publication of this notice.[2] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[3] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

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 Enforcement and Compliance, U.S. Department of Commerce. All documents must be filed electronically using ACCESS. An electronically filed request must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Standard Time, within 30 days after the date of publication of this notice.[4] Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date,

[1] For a complete description of the scope, *see Antidumping Duty Orders: Lightweight Thermal Paper from Germany and the People's Republic of China,* 73 FR 70959 (November 24, 2008) (*Order*); *see also* ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Lightweight Thermal Paper from Germany,'' dated concurrently with this notice (Preliminary Decision Memorandum).

[2] *See* 19 CFR 351.309(c).

[3] *See* 19 CFR 351.309(d).

[4] *See* 19 CFR 351.310(c).

time, and location of the hearing two days before the scheduled date.

The Department intends to issue the final results of this administrative review, including the results of its analysis of 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 shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[5]

If Koehler's weighted-average dumping margin is above *de minimis* (*i.e.,* 0.50 percent) in the final results of this review, we will calculate an importer-specific per-unit duty assessment rate by aggregating the total amount of antidumping duties calculated for the examined sales and dividing this amount by the total quantity of those sales, because Koehler did not report entered value for all its U.S. sales. To determine whether this duty assessment rate is *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we will calculate an importer-specific *ad valorem* ratio based on the estimated entered value.

We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is above *de minimis.* Where either Koehler's weighted-average dumping margin is zero or *de minimis,* or the importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[6]

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. This clarification will apply to entries of subject merchandise during the POR produced by Koehler for which it did not know its merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. For a full discussion of this clarification, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

We intend to issue instructions to CBP 15 days after the publication date of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Koehler will be the rate established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not participating in this review, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 6.50 percent, the all-others rate established in the less-than-fair-value investigation.[7] These 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) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 21, 2104.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

1. Scope of the Order
2. Fair Value Comparisons
   A. Determination of Comparison Method
   B. Results of the Differential Pricing Analysis
3. Product Comparisons
4. Export Price and Constructed Export Price
5. Normal Value
   A. Home Market Viability and Selection of Comparison Market
   B. Level of Trade
   C. Cost of Production Analysis
   D. Calculation of Normal Value Based on Comparison-Market Prices
6. Currency Conversion
7. Duty Absorption

[FR Doc. 2014–28260 Filed 11–28–14; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–501]

Welded Carbon Steel Standard Pipe and Tube Products From Turkey: Final Results of Antidumping Duty Administrative Review; 2012–2013

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On June 25, 2014, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on welded carbon steel standard pipe and tube products (welded pipe and tube) from Turkey.[1] The period of review (POR) is May 1, 2012, through April 30, 2013. Based on our analysis of the comments received, we have made no changes in the margin calculations. Therefore, the final results do not differ from the *Preliminary Results.* The final weighted-average dumping margins for the reviewed firms are listed below in the section entitled ''Final Results of the Review.'' Further, unchanged from the *Preliminary Results,* we continue to find that various companies had no shipments of subject merchandise during the POR.

DATES: *Effective Date:* December 1, 2014.

[5] *See* 19 CFR 351.212(b).

[6] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012); 19 CFR 351.106(c)(2).

[7] *Lightweight Thermal Paper from Germany: Notice of Final Determination of Sales at Less Than Fair Value,* 73 FR 57326, 57328 (October 2, 2008).

[1] *See Welded Carbon Steel Standard Pipe and Tube Products From Turkey: Preliminary Results of Antidumping Duty Administrative Review; 2012–2013,* 79 FR 35999 (June 25, 2014) (*Preliminary Results*), and the accompanying Preliminary Decision Memorandum (PDM).

FOR FURTHER INFORMATION CONTACT: Victoria Cho, Fred Baker, or Robert James, AD/CVD Operations, Office VI, Enforcement and Compliance International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC, 20230; telephone (202) 482–5075, (202) 482–2924, or (202) 482–0649, respectively.

Background

On June 25, 2014, the Department published the *Preliminary Results,* and invited interested parties to comment.[2] On July 30, 2014, we received case briefs from the petitioner, Wheatland Tube Company (Wheatland), and one respondent, Borusan Mannesmann Boru Sanayi ve Ticaret A.S. (Borusan).[3] On August 6, 2013, we received rebuttal briefs from Wheatland and Borusan.

The Department has conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The merchandise subject to the order is welded pipe and tube. The welded pipe and tube subject to the order is currently classifiable under subheading 7306.30.1000, 7306.30.5025, 7306.30.5032, 7306.30.5040, 7306.30.5055, 7306.30.5085, and 7306.30.5090 of the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS subheadings are provided for convenience and customs purposes. The written description is dispositive.

A full written description of the scope of the order is contained in the memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review: Welded Carbon Steel Standard Pipe and Tube Products from Turkey; 2012–2013'' (Issues and Decision Memorandum), which is hereby adopted by this notice and incorporated herein by reference. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and it is available to all parties in the Central Records Unit, Room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Determination of No Shipments

In the *Preliminary Results,* the Department preliminarily determined the following companies had no shipments during the POR: the Borusan Group, Borusan Holding A.S., Cayirova Boru Sanayi ve Ticaret A.S., ERBOSAN Erciyas Boru Sanayi ve Ticaret A.S., Guven Celik Boru San. ve Tic. Ltd., Guven Steel Pipe, Metaleks Celik Urunleri San. ve Tic. Ltd. Sti., Metaliks Celik Urunkeri San. ve Tic. Ltd., Toscelik Metal Ticaret A.S., Toscelik Profil ve Sac Endustrisi A.S., Umran Celik Boru Sanayii A.S., Umran Steel Pipe Inc., Yucel Boru ve Profil Endustrisi A.S, Yucelboru Ihracat Ithalat ve Pazarlama A.S., and Yucel Group.[4] Following publication of the *Preliminary Results,* we received no comments from interested parties regarding these companies. As a consequence, and because the record contains no evidence to the contrary, we continue to find that none of these companies made shipments during the POR. Accordingly, consistent with the Department's practice, we intend to instruct U.S. Customs and Border Protection (CBP) to liquidate any existing entries of merchandise produced by these companies, but exported by other parties, at the all-others rate.[5]

Analysis of Comments Received

All issues raised in the case briefs by parties are addressed in the Issues and Decision Memorandum. A list of the issues which parties raised and to which we respond in the Issues and Decision Memorandum is attached to this notice as an Appendix.

Changes Since the Preliminary Results

Based on a review of the record and our analysis of the comments received from interested parties on the *Preliminary Results,* we have made no changes to the margin calculations.[6]

Final Results of the Review

As a result of this review, we determine that the following weighted-average dumping margins exist for the period May 1, 2012, through April 30, 2013:

Manufacturer/exporter	Weighted-average dumping margin (percent)
Borusan Mannesmann Boru Sanayi ve Ticaret A.S.[7]	1.28
Toscelik Profil ve Sac Endustrisi A.S.[8]	0.00

Disclosure

We intend to disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Assessment Rates

The Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b). The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review in the **Federal Register**.

For Borusan, because its weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent), the Department has calculated importer-specific antidumping duty assessment rates. We calculated importer-specific *ad valorem* antidumping duty assessment rates by aggregating the total amount of dumping calculated for the examined sales of each importer and dividing each of these amounts by the total entered value associated with those sales. We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review where an importer-specific assessment rate is not zero or *de minimis.* Pursuant to 19 CFR 351.106(c)(2), we will instruct CBP to liquidate without regard to antidumping duties any entries for which the importer-specific assessment rate is zero or *de minimis.*

For Toscelik Profil ve Sac Endustrisi A.S. (Toscelik), we will instruct CBP to

[2] *See Preliminary Results,* 79 FR at 36000.

[3] As explained in the *Preliminary Results,* the Department treats Borusan, Borusan Istikbal Ticaret T.A.S., and Borusan Lojistik Dagitim Depolama Tasimacilik ve Tic A.S. as the same legal entity. *See* 79 FR at 35999 and n.3.

[4] *See Preliminary Results,* 79 FR at 35999 and the accompanying PDM at 3–4.

[5] *See, e.g., Magnesium Metal From the Russian Federation: Preliminary Results of Antidumping Duty Administrative Review,* 75 FR 26922, 26923 (May 13, 2010) (*Magnesium Metal*), unchanged in *Magnesium Metal From the Russian Federation: Final Results of Antidumping Duty Administrative Review,* 75 FR 56989 (September 17, 2010).

[6] *See* the Issues and Decision Memorandum.

[7] *See* footnote 3.

[8] As explained in the *Preliminary Results,* the Department treats Toscelik Profil ve Sac Endustrisi A.S. and Tosyali Dis Ticaret A.S. as the same legal entity. *See Preliminary Results,* 79 FR at 35999 & n.3. However, the Department no longer includes Toscelik Metal Ticaret A.S. as part of this entity because it ceased to exist prior to the POR. *Id.*

liquidate its entries during the POR imported by the importer identified in its questionnaire responses without regard to antidumping duties because its weighted-average dumping margin in these final results is zero.[9]

The Department clarified its ''automatic assessment'' regulation on May 6, 2003.[10] This clarification applies to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed companies did not know that the merchandise they sold to an intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate established in the less-than-fair-value (LTFV) investigation [11] if there is no rate for the intermediate company(ies) involved in the transaction.[12]

For the companies identified above as having had no shipments, because the Department has determined that each of these companies had no shipments during the POR for which they had knowledge, all entries entered under each of their cash deposit rates will be liquidated at the all-others rate established in the LTFV investigation.[13]

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rates for Borusan and Toscelik will be equal to the weighted-average dumping margins established in the final results of this review; (2) for previously reviewed or investigated companies not participating in this review, the cash deposit rate will continue to be the company-specific rate established from a completed segment of this proceeding for the most recent period; (3) if the exporter is not a firm covered in this review, a previous review, or the original LTFV investigation, but the manufacturer is, the cash deposit rate will be the rate established from a completed segment of this proceeding for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 14.74 percent, the all-others rate established in the LTFV investigation.[14] These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred, and the subsequent assessment of double antidumping duties.

Notifications to Interested Parties

In accordance with 19 CFR 351.305(a)(3), this notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO. Timely written notification of return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

These final results of review and notice are published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 21, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

Summary
Background
Scope of the Order
Discussion of the Issues
Issue 1: Physical Characteristic for Grade
Issue 2: Whether the Department Should Collapse ASTM A53 grade A and ASTM A53 grade B into a Single Grade Category
Issue 3: Duty Drawback and Treatment of the Resource Utilization Support Fund Tax
Issue 4: Duty Drawback and Yield Loss Factor
Issue 5: Differential Pricing
Issue 6: Withdrawal of the Regulatory Provisions Governing Targeted Dumping in Less-Than-Fair-Value Investigations
Recommendation

[FR Doc. 2014–28263 Filed 11–28–14; 8:45 am]

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[9] *See Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8103 (February 14, 2012).

[10] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) (*Assessment Policy Notice*).

[11] *See Antidumping Duty Order; Welded Carbon Steel Standard Pipe and Tube Products From Turkey,* 51 FR 17784, 17784 (May 15, 1986) (*Order*).

[12] *See* Assessment Policy Notice for a full discussion of this clarification.

[13] *See Magnesium Metal,* 75 FR at 26923; *Assessment Policy Notice,* 68 FR 23954; *see also Order,* 51 FR at 17784.

[14] *See Order,* 51 FR at 17784.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–964]

Seamless Refined Copper Pipe and Tube From the People's Republic of China: Preliminary Results and Partial Rescission of Administrative Review; 2012–2013

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In response to requests from interested parties, the Department of Commerce (the ''Department'') is conducting the third administrative review of the antidumping duty order on seamless refined copper pipe and tube from the People's Republic of China (''PRC''), covering the period November 1, 2012 through October 31, 2013. The Department preliminarily determines that, during the period of review, Golden Dragon Precise Copper Tube Group, Inc., Hong Kong GD Trading Co., Ltd., and Golden Dragon Holding (Hong Kong) International, Ltd. (collectively, ''Golden Dragon''), the respondent in this proceeding, has made sales of subject merchandise at less than normal value (''NV''). Interested parties are invited to comment on these preliminary results.

DATES: *Effective Date:* December 1, 2014.

FOR FURTHER INFORMATION CONTACT: James Martinelli, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–2923.

SUPPLEMENTARY INFORMATION:

Scope of Order

The merchandise subject to the order is seamless refined copper pipe and tube. The product is currently classified under Harmonized Tariff Schedule of the United States (''HTSUS'') item numbers 7411.10.1030 and 7411.10.1090. Products subject to this order may also enter under HTSUS item numbers 7407.10.1500, 7419.99.5050, 8415.90.8065, and 8415.90.8085. Although the HTSUS numbers are

provided for convenience and customs purposes, the written description of the scope of this order remains dispositive.[1]

Extension of Deadlines for Preliminary Results

On July 8, 2014 the Department extended the time period for issuing the preliminary results of this review by 120 days, until December 1, 2014.[2]

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. The Department is rescinding this review with regard to Luvata Tube (Zhongshan) Ltd. & Luvata Alltop (Zhongshan) Ltd. (collectively, ''Luvata''), Shanghai Hailiang Copper Co., Ltd., and Zhejiang Hailiang Co., Ltd. as parties have timely withdrawn all review requests with respect to these companies. At the time of Initiation, Luvata, Shanghai Hailiang Copper Co., Ltd., and Zhejiang Hailiang Co., Ltd. had a separate rate from a prior completed segment of this proceeding.[3] Because we are now rescinding this review for these companies, we will instruct CBP to liquidate their entries at the rates of the cash deposits of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(2).

Reviews were also requested for 11 additional companies listed in the *Initiation Notice,* and those requests were also timely withdrawn.[4] However, we are not rescinding the reviews for these 11 companies at this time because they do not have a separate rate and, therefore, each currently remains part of the PRC-wide entity. The PRC-wide entity is currently subject to this administrative review.[5]

Methodology

The Department conducted this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the ''Act''). Export prices and constructed export prices were calculated in accordance with section 772 of the Act. Because the PRC is a nonmarket economy (''NME'') country within the meaning of section 771(18) of the Act, NV has been calculated in accordance with section 773(c) of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum, which is hereby adopted by this notice. A list of topics discussed in the Preliminary Decision Memorandum is included as an Appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''). ACCESS is available to registered users at *http://access.trade.gov,* and it is available to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed at *http://enforcement.trade.gov/frn/index.html.* The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Preliminary Results of Review

The Department preliminarily determines that the following weighted-average dumping margins exist:

Exporter	Weighted-average dumping margin (percent)
Golden Dragon Precise Copper Tube Group, Inc., Hong Kong GD Trading Co., Ltd., and Golden Dragon Holding (Hong Kong) International, Ltd.	7.17
PRC-wide entity	60.85

Disclosure and Public Comment

The Department intends to disclose calculations performed for these preliminary results to the parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties may submit written comments no later than 30 days after the date of publication of these preliminary results.[6] Rebuttals to written comments may be filed no later than five days after the written comments are filed.[7]

Any interested party may request a hearing within 30 days of publication of this notice.[8] Hearing requests should contain the following information: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230.[9]

All submissions by interested parties must be filed electronically via ACCESS. An electronically filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS, by

[1] *See* Memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, regarding ''Decision Memorandum for the Preliminary Results of the 2012–2013 Administrative Review of the Antidumping Duty Order on Seamless Refined Copper Pipe and Tube from the People's Republic of China'' (November 21, 2014) for a complete description of the scope of the order (''Preliminary Decision Memorandum'').

[2] *See* Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, through Abdelali Elouaradia, Office Director, Antidumping and Countervailing Duty Operations, Office 4, from Maisha Cryor, International Trade Compliance Analyst, Antidumping and Countervailing Duty Operations, Office 4, regarding ''Seamless Refined Copper Pipe and Tube from the People's Republic of China: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review'' (July 8, 2014).

[3] *See Seamless Refined Copper Pipe and Tube From Mexico and the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 75 FR 60725, 60729 (October 1, 2010) (''*LTFV Final Determination*'').

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 78 FR 79392 (December 30, 2013) (''*Initiation Notice*''). The 11 companies include: China Hailiang Metal Trading, Foshan Hua Hong Copper Tube Co., Ltd., Guilin Lijia Metals Co., Ltd., Hong Kong Hailiang Metal, Ningbo Jintian Copper Tube Co., Ltd., Shanghai Hailiang Metal Trading Limited, Sinochem Ningbo Ltd. & Sinochem Ningbo Import & Export Co., Ltd., Taicang City Jinxin Copper Tube Co., Ltd., Zhejiang Jihe Pipes Inc., and Zhejiang Naile Copper Co., Ltd. These companies are not included in the collapsed entity of Hong Kong Hailiang Metal Trading Limited, Zhejiang Hailiang Co., Ltd., and Shanghai Hailiang Copper Co., Ltd.

[5] *See, e.g., Narrow Woven Ribbons With Woven Selvedge From the People's Republic of China: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review,* 77 FR 47363, 47365 (August 8, 2012), unchanged in *Narrow Woven Ribbons With Woven Selvedge From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2010–2011,* 78 FR 10130 (February 13, 2013). A change in practice with respect to the conditional review of the PRC-wide entity is not applicable to this administrative review. *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65964, 65969–70 (November 4, 2013) (apply the change in practice to reviews for which the notice of opportunity to request an administrative review is published on or after December 4, 2013).

[6] *See* 19 CFR 351.309(c).

[7] *See* 19 CFR 351.309(d).

[8] *See* 19 CFR 351.310(c).

[9] *See* 19 CFR 351.310(d).

5 p.m. Eastern Time in order for it to have been submitted timely on that day.

The Department intends to issue the final results of this administrative review, which will include the results of its analysis of issues raised in any written comments, within 120 days of publication of these preliminary results unless extended, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuing the final results of the review, the Department shall determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review. For any individually examined respondents whose weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent), the Department will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[10] For respondents not individually examined for this review, their *ad valorem* assessment rate will be equal to their weighted-average dumping margin established in the final results of review.

The Department will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is not zero or *de minimis.* Where either the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* the Department will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

The Department announced a refinement to its assessment practice in NME cases. Pursuant to this refinement in practice, for entries that were not reported in the U.S. sales databases submitted by companies individually examined during this review, the Department will instruct CBP to liquidate such entries at the PRC-wide rate. In addition, if the Department determines 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.[11]

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated antidumping duties.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this review (except, if the rate is *de minimis,* then the cash deposit rate will be zero for that exporter); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding; (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 60.85 percent, which is the rate for the PRC-wide entity; [12] 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 that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice 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 review period. Failure to comply with this requirement could result in the CBP assessing double antidumping duties based on the Department's presumption that antidumping duties were reimbursed.

Notification to Interested Parties

This administrative review and notice are in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.213.

Dated: November 21, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Discussion of the Methodology
5. Partial Rescission of Administrative Review
6. Non-Market Economy Country Status
7. Separate Rates
8. PRC-Wide Entity
9. Surrogate Country
10. Date of Sale
11. Fair Value Comparisons
12. Determination of Comparison Method
13. Export Price
14. Constructed Export Price
15. Value Added Tax
16. Normal Value
17. Factor Valuations
18. Currency Conversion
19. Recommendation

[FR Doc. 2014–28255 Filed 11–28–14; 8:45 am]

BILLING CODE 3510–DS–P

[10] In these preliminary results, the Department applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

[11] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

[12] *See LTFV Final Determination,* 75 FR at 60729.

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Five-Year (''Sunset'') Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In accordance with section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department of Commerce (''the Department'') is automatically initiating the five-year review (''Sunset Review'') of the antidumping and countervailing duty (''AD/CVD'') orders listed below. The International Trade Commission (''the Commission'') is publishing concurrently with this notice its notice of *Institution of Five-Year Review* which covers the same orders.

DATES: *Effective Date:* December 1, 2014.

FOR FURTHER INFORMATION CONTACT: The Department official identified in the *Initiation of Review* section below at AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230. For information from the Commission

contact Mary Messer, Office of Investigations, U.S. International Trade Commission at (202) 205–3193.

SUPPLEMENTARY INFORMATION:

Background

The Department's procedures for the conduct of Sunset Reviews are set forth in its *Procedures for Conducting Five-Year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders,* 63 FR 13516 (March 20, 1998) and 70 FR 62061 (October 28, 2005). Guidance on methodological or analytical issues relevant to the Department's conduct of Sunset Reviews is set forth in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012).

Initiation of Review

In accordance with 19 CFR 351.218(c), we are initiating Sunset Reviews of the following antidumping and countervailing duty orders:

DOC case No.	ITC case No.	Country	Product	Department contact
A–570–943 [1]	731–TA–1159 ...	PRC	Oil Country Tubular Goods (1st Review)	Jacqueline Arrowsmith, (202) 482–5255.
C–570–944	701–TA–463	PRC	Oil Country Tubular Goods (1st Review)	David Goldberger, (202) 482–4136.

[1] On November 3, 2014, the Department published the *Antidumping or Countervailing Duty Order, Finding or Suspended Investigation; Advance Notification of Sunset Reviews,* which listed the wrong case number for the antidumping duty order on Oil Tubular Goods from the PRC. *See* 79 FR 65189 (November 3, 2014). The correct case number for this case is A–570–943, as listed above.

Filing Information

As a courtesy, we are making information related to sunset proceedings, including copies of the pertinent statute and Department's regulations, the Department's schedule for Sunset Reviews, a listing of past revocations and continuations, and current service lists, available to the public on the Department's Web site at the following address: ''*http://enforcement.trade.gov/sunset/.*'' All submissions in these Sunset Reviews must be filed in accordance with the Department's regulations regarding format, translation, and service of documents. These rules, including electronic filing requirements via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''), can be found at 19 CFR 351.303.[2]

Revised Factual Information Requirements

This notice serves as a reminder that any party submitting factual information in an AD/CVD proceeding must certify to the accuracy and completeness of that information.[3] Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives in all AD/CVD investigations or proceedings initiated on or after August 16, 2013.[4] The formats for the revised certifications are provided at the end of the *Final Rule.* The Department intends to reject factual submissions if the submitting party does not comply with the revised certification requirements.

On April 10, 2013, the Department published *Definition of Factual Information and Time Limits for Submission of Factual Information: Final Rule,* 78 FR 21246 (April 10, 2013), which modified two regulations related to antidumping and countervailing duty proceedings: The definition of factual information (19 CFR 351.102(b)(21)), and the time limits for the submission of factual information (19 CFR 351.301). The final rule identifies five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). The final rule requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The final rule also modified 19 CFR 351.301 so that, rather than providing general time limits, there are specific time limits based on the type of factual information being submitted. These modifications are effective for all segments initiated on or after May 10, 2013. Review the final rule, available at *http://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt,* prior to submitting factual information in this segment. To the extent that other regulations govern the submission of factual information in a segment (such as 19 CFR 351.218), these time limits will continue to be applied.

Revised Extension of Time Limits Regulation

On September 20, 2013, the Department modified its regulation at 19 CFR 351.302(c) concerning the extension of time limits for submissions in antidumping and countervailing duty proceedings: *Extension of Time Limits,* 78 FR 57790 (September 20, 2013). The modification clarifies that parties may request an extension of time limits before a time limit established under part 351 of the Department's regulations expires, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the time limit established under part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Under certain circumstances, the Department may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, the Department will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This modification also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the circumstances under which the Department will grant untimely-filed requests for the extension of time

[2] *See also Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[3] *See* section 782(b) of the Act.

[4] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (''*Final Rule*'') (amending 19 CFR 351.303(g)).

limits. These modifications are effective for all segments initiated on or after October 21, 2013. Review the final rule, available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these segments.

Letters of Appearance and Administrative Protective Orders

Pursuant to 19 CFR 351.103(d), the Department will maintain and make available a public service list for these proceedings. Parties wishing to participate in any of these five-year reviews must file letters of appearance as discussed at 19 CFR 351.103(d)). To facilitate the timely preparation of the public service list, it is requested that those seeking recognition as interested parties to a proceeding submit an entry of appearance within 10 days of the publication of the Notice of Initiation.

Because deadlines in Sunset Reviews can be very short, we urge interested parties who want access to proprietary information under administrative protective order (''APO'') to file an APO application immediately following publication in the **Federal Register** of this notice of initiation. The Department's regulations on submission of proprietary information and eligibility to receive access to business proprietary information under APO can be found at 19 CFR 351.304–306.

Information Required From Interested Parties

Domestic interested parties, as defined in section 771(9)(C), (D), (E), (F), and (G) of the Act and 19 CFR 351.102(b), wishing to participate in a Sunset Review must respond not later than 15 days after the date of publication in the **Federal Register** of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii). In accordance with the Department's regulations, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, the Department will automatically revoke the order without further review.[5]

If we receive an order-specific notice of intent to participate from a domestic interested party, the Department's regulations provide that *all parties* wishing to participate in a Sunset Review must file complete substantive responses not later than 30 days after the date of publication in the **Federal Register** of this notice of initiation. The required contents of a substantive response, on an order-specific basis, are set forth at 19 CFR 351.218(d)(3). Note that certain information requirements differ for respondent and domestic parties. Also, note that the Department's information requirements are distinct from the Commission's information requirements. Consult the Department's regulations for information regarding the Department's conduct of Sunset Reviews. Consult the Department's regulations at 19 CFR part 351 for definitions of terms and for other general information concerning antidumping and countervailing duty proceedings at the Department.

This notice of initiation is being published in accordance with section 751(c) of the Act and 19 CFR 351.218(c).

Dated: November 19, 2014.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2014–28408 Filed 11–28–14; 8:45 am]

BILLING CODE 3510–DS–P

[5] *See* 19 CFR 351.218(d)(1)(iii).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–017]

Countervailing Duty Investigation of Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China: Preliminary Affirmative Determination, Preliminary Affirmative Critical Circumstances Determination, in Part, and Alignment of Final Determination With Final Antidumping Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) preliminarily determines that countervailable subsidies are being provided to producers and exporters of passenger vehicle and light truck tires (passenger tires) from the People's Republic of China (PRC). The period of investigation is January 1, 2013, through December 31, 2013. We invite interested parties to comment on this preliminary determination.

DATES: *Effective Date:* Insert date of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Emily Halle or Jason Rhoads, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone 202.482.0176, 202.482.0123, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Investigation

The products covered by this investigation are certain passenger tires from the PRC. For a complete description of the scope of this investigation, *see* the Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations to Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Countervailing Duty Investigation of Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China: Decision Memorandum for the Preliminary Determination,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum). The Preliminary Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://trade.gov/enforcement.* The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Methodology

The Department is conducting this countervailing duty (CVD) investigation in accordance with section 701 of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[1] For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.

The Department notes that, in making these findings, we relied, in part, on facts available and, because one or more respondents did not act to the best of their ability to respond to the Department's requests for information, we drew an adverse inference where appropriate in selecting from among the

[1] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

facts otherwise available.[2] For further information, *see* ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Decision Memorandum.

Alignment

As noted in the Preliminary Decision Memorandum, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), we are aligning the final CVD determination in this investigation with the final determination in the companion antidumping duty (AD) investigation of passenger tires from the PRC based on a request made by Petitioner.[3] Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than April 6, 2015, unless postponed.

Critical Circumstances, in Part

In accordance with section 703(e)(1) of the Act, we preliminarily find that critical circumstances exist with respect to imports of passenger tires from the PRC for Shandong Yongsheng Rubber Group Co., Ltd. (Yongsheng) and all other exporters or producers not individually examined. A discussion of our determination can be found in the Preliminary Decision Memorandum.

Preliminary Determination and Suspension of Liquidation

In accordance with section 703(d)(1)(A)(i) of the Act, we calculated an individual estimated countervailable subsidy rate for the individually-investigated exporters/producers of the subject merchandise.[4] We also calculated an all-others rate. In accordance with sections 703(d) and 705(c)(5)(A) of the Act, for companies not individually investigated, we apply an ''all-others'' rate, which is normally calculated by weighting the subsidy rates of the individual companies selected as mandatory respondents by those companies' exports of the subject merchandise to the United States. Under section 705(c)(5)(A)(i) of the Act, the all-others rate excludes zero and *de minimis* rates calculated for the exporters and producers individually investigated as well as rates based entirely on facts otherwise available. Therefore, we have excluded the rate for Yongsheng from the all-others rate. Notwithstanding the language of section 705(c)(5)(A)(i) of the Act, we have not calculated the ''all-others'' rate by weight averaging the rates of the two individually investigated respondents, because doing so risks disclosure of proprietary information. Therefore, and consistent with the Department's practice where such risk exists, for the ''all-others'' rate, we calculated a weight average of the two responding firms' rates using publicly ranged data.[5] The overall preliminary estimated countervailable subsidy rates are summarized in the table below:

Exporter/Producer	Subsidy rate (%)
GITI Tire (Fujian) Co., Ltd. and certain cross-owned companies	17.69
Cooper Kunshan Tire Co., Ltd and certain cross-owned companies	12.50
Shandong Yongsheng Rubber Group Co., Ltd.	81.29
All-Others	15.69

In accordance with sections 703(d)(1)(B) and (d)(2) of the Act, we are directing U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of passenger tires from the PRC that are entered, or withdrawn from warehouse, for consumption on or after the date of the publication of this notice in the **Federal Register**, and to require a cash deposit for such entries of merchandise in the amounts indicated above. Moreover, because we preliminarily find critical circumstances exist with respect to Yongsheng, and all other exporters or producers not individually examined, in accordance with section 703(e)(2)(A) of the Act, we are directing CBP to apply the suspension of liquidation to any unliquidated entries entered, or withdrawn from warehouse for consumption by these companies, on or after the date which is 90 days prior to the date of publication of this notice in the **Federal Register**.

Verification

As provided in section 782(i)(1) of the Act, we intend to verify the information submitted by the respondents prior to making our final determination.

Disclosure and Public Comment

The Department intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement.[6] Interested parties may submit case and rebuttal briefs, as well as request a hearing.[7] For a schedule of the deadlines for filing case briefs, rebuttal briefs, and hearing requests, *see* the Preliminary Decision Memorandum.

International Trade Commission Notification

In accordance with section 703(f) of the Act, we will notify the International Trade Commission (ITC) of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information relating to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Assistant Secretary for Enforcement and Compliance.

In accordance with section 705(b)(2) of the Act, if our final determination is affirmative, the ITC will make its final determination within 45 days after the Department makes its final determination.

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: November 21, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope Comments
IV. Scope of the Investigation
V. Alignment
VI. Respondent Selection
VII. Preliminary Determination of Critical Circumstances, in Part
VIII. Injury Test
IX. Application of the Countervailing Duty Law to Imports from the PRC

[2] *See* sections 776(a) and (b) of the Act.

[3] Collectively, United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC. *See* Letter from Petitioner, ''Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China—Petitioner's Request for Alignment of Countervailing Duty Investigation Final Determination Deadline with Antidumping Investigation Final Determination Deadline,'' November 5, 2014.

[4] The individually-investigated exporters/producers are GITI Tire (Fujian) Co., Ltd., and its cross-owned affiliated companies GITI Tire (China) Investment Company Ltd., GITI Radial Tire (Anhui) Company Ltd., GITI Tire (Hualin) Company Ltd., GITI Steel Cord (Hubei) Company Ltd., and Anhui Prime Cord Fabrics Company Ltd.; and Cooper Kunshan Tire Co., Ltd., and its cross-owned affiliated company, Cooper Chengshan (Shandong) Tire Co., Ltd.

[5] *See, e.g., Hardwood and Decorative Plywood from the People's Republic of China: Final Affirmative Countervailing Duty Determination; 2011,* 78 FR 58283 (September 23, 2013).

[6] *See* 19 CFR 351.224(b).

[7] *See* 19 CFR 351.309(c)–(d), 19 CFR 351.310(c).

X. Subsidies Valuation
XI. Benchmarks and Discount Rates
XII. Use of Facts Otherwise Available and Adverse Inferences
XIII. Analysis of Programs
XIV. ITC Notification
XV. Disclosure and Public Comment
XVI. Verification
XVII. Conclusion

[FR Doc. 2014–28257 Filed 11–28–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD645

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's (Council) Observer Policy Committee will meet to review scientific information affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Wednesday, December 17, 2014, beginning at 9:30 a.m.

ADDRESSES: The meeting will be held at the Sheraton Colonial Hotel; One Audubon Road; Wakefield, MA 01880; telephone: (781) 245–9300; fax: (781) 245–0842.

Council Address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda Items

The Observer Policy Committee will meet to: Review progress regarding development of NMFS-led omnibus amendment to establish provisions for industry-funded monitoring (IFM) across all Council-managed fisheries; review and discuss timeline for IFM amendment; discuss details of omnibus IFM amendment alternatives, review related information and available analyses, and develop Committee recommendations; and plan next meeting and address other business 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 Thomas A. Nies (see **ADDRESSES**) at least 5 days prior to the meeting date.

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

Dated: November 25, 2014.

Tracey L. Thompson,

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

[FR Doc. 2014–28202 Filed 11–28–14; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Wednesday, December 3, 2014, 10:00 a.m.–12:00 p.m.

PLACE: CPSC's National Product Testing and Evaluation Center, 5 Research Place, Rockville, MD 20850.

STATUS: Commission Meeting—Open to the Public.

MATTER TO BE CONSIDERED: Briefing Matter: Fiscal Year 2015 Operating Plan.

A live webcast of the Meeting can be viewed at *www.cpsc.gov/live.*

CONTACT PERSON FOR MORE INFORMATION: Todd A. Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7923.

Dated: November 26, 2014.

Alberta E. Mills,

Acting Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2014–28385 Filed 11–26–14; 4:15 pm]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Friday, December 5, 2014, 9:00 a.m.–12:00 p.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Commission Meeting—Open to the Public.

MATTER TO BE CONSIDERED: Briefing Matter: Phthalates—NPR.

A live webcast of the Meeting can be viewed at *www.cpsc.gov/live.*

CONTACT PERSON FOR MORE INFORMATION: Todd A. Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7923.

Dated: November 25, 2014.

Alberta E. Mills,

Acting Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2014–28386 Filed 11–26–14; 4:15 pm]

BILLING CODE 6355–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, CNCS is soliciting comments concerning its proposed new information collection through the Partnership and Collaboration (PAC) Survey that is part of the Social Network Study (SNS). The goal of this study is to gather a comprehensive understanding of network of organizations in the same service area as CNCS grantees, the relationships and interactions of CNCS grantees with these other organizations, and how central the AmeriCorps members and member organizations are to these networks. In support of these efforts, we will design and field a survey of grantees and organizations in the service area in several sites, the data from

which will be the foundation for social network analysis. CNCS will analyze the resulting data, which will produce quantitative mapping of networks and measure the networks' formal properties—notably the strength, intensity, frequency, and direction of the network relations. Participation in data collection efforts is not required to be considered to obtain support from CNCS.

Copies of the information collection request can be obtained by contacting the office listed in the **ADDRESSES** section of this Notice.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by January 30, 2015.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) *By mail sent to:* Corporation for National and Community Service, Office of Research and Evaluation; Attention Anthony Nerino, Research Associate, Rm. #10913A; 1201 New York Avenue NW., Washington, DC 20525.

(2) *By hand delivery or by courier* to the CNCS mailroom at Room 8100 at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) *Electronically* through *www.regulations.gov.*

Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Anthony Nerino, (202–606–3913), or by email at *anerino@cns.gov.*

SUPPLEMENTARY INFORMATION: CNCS is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, 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 expected to respond, including 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).

Background

While previous evaluation efforts have confirmed CNCS's impact on members and recipients of services such as increased education, skills, and civic participation, the Social Network Study (SNS) will be a feasibility study of a tool designed to evaluate the collaboration and partnerships between ACSN grantees and organizations within their geographic communities. The main goal of SNS is to gather through the Partnership and Collaboration (PAC) Survey an in-depth understanding of how ACSN grantees engage organizational communities through partnerships and to learn more about their relationships and interactions with other organizations within their network. The PAC will also provide information about both the barriers that prevent collaboration and interaction, and facilitators that could be utilized to overcome them. These outcomes are an important step to developing a more vigorous civic infrastructure and increasing capacity in the communities served by CNCS and its grantees. This study will also help CNCS disseminate best practices about collaboration and partnerships to other AmeriCorps programs. Information will be collected electronically via Web primarily and telephone and mail in options will be provided only to those not responsive to the Web survey.

Current Action

This is a new information collection request.

Type of Review: New.

Agency: Corporation for National and Community Service.

Title: AmeriCorps State and National Partnership and Collaboration (PAC) Survey.

OMB Number: None.

Agency Number: None.

Affected Public: AmeriCorps grantees and their community partners.

Total Respondents: 250.

Frequency: Once.

Average Time per Response: 30 minutes.

Estimated Total Burden Hours: 125.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: November 24, 2014.

Mary Hyde,

Deputy Director, Office of Research and Evaluation.

[FR Doc. 2014–28177 Filed 11–28–14; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2012–OS–0004]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by December 31, 2014.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: Department of Defense Education Activity (DoDEA) School Perception Surveys; OMB Control Number 0704–TBD.

Type of Request: New.

Number of Respondents: 3457.

Responses per Respondent: 1.

Annual Responses: 3457.

Average Burden per Response: 20 minutes.

Annual Burden Hours: 1152.

Needs and Uses: The information collection requirement is necessary to measure the satisfaction level of sponsors and students with the programs and services provided by DoDEA. This collection is necessary to measure school environment within Goal 2 of the DoDEA Community Strategic Plan (SY2013–14–2017/18), which states that DoDEA will ''Develop and sustain each school to be high-performing with an environment of innovation, collaboration, continuous renewal and caring relationships.'' The surveys are also necessary to measure perceptions of teacher quality within Goal 3 of the DoDEA Community Strategic Plan which states that DoDEA will ''Recruit, develop, and empower a diverse high-performing team to maximize achievement for each student.''

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

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

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

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

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

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: November 24, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–28166 Filed 11–28–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the Uniform Formulary Beneficiary Advisory Panel

AGENCY: Assistant Secretary of Defense (Health Affairs), DoD.

ACTION: Notice of meeting.

SUMMARY: The Department of Defense is publishing this notice to announce a Federal Advisory Committee meeting of the Uniform Formulary Beneficiary Advisory Panel (hereafter referred to as the Panel).

DATES: Thursday, January 8, 2015, from 9:00 a.m. to 1:00 p.m.

ADDRESSES: Naval Heritage Center Theater, 701 Pennsylvania Avenue NW., Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Col J. Michael Spilker, DFO, Uniform Formulary Beneficiary Advisory Panel, 7700 Arlington Boulevard, Suite 5101, Falls Church, VA 22042–5101. Telephone: (703) 681–2890. Fax: (703) 681–1940. Email Address: *Baprequests@dha.mil.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 United States Code (U.S.C.) Appendix, as amended) and the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended).

Purpose of Meeting: The Panel will review and comment on recommendations made to the Director of Defense Health Agency, by the Pharmacy and Therapeutics Committee, regarding the Uniform Formulary.

Meeting Agenda

1. Sign-In.
2. Welcome and Opening Remarks.
3. Public Citizen Comments.
4. Scheduled Therapeutic Class Reviews (Comments will follow each agenda item) .
   a. Multiple Sclerosis Agents.
   b. Self-Monitoring Blood Glucose Strips.
5. Designated Newly Approved Drugs in Already-Reviewed Classes.
6. Pertinent Utilization Management Issues.
7. Panel Discussions and Vote.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b, as amended, and 41 Code of Federal Regulations (CFR) 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is limited and will be provided only to the first 220 people signing-in. All persons must sign-in legibly.

Administrative Work Meeting: Prior to the public meeting, the Panel will conduct an Administrative Work Meeting from 8:00 a.m. to 9:00 a.m. to discuss administrative matters of the Panel. The Administrative Work Meeting will be held at the Naval Heritage Center, 701 Pennsylvania Avenue NW., Washington, DC 20004. Pursuant to 41 CFR 102–3.160, the Administrative Work Meeting will be closed to the public.

Written Statements: Pursuant to 41 CFR 102–3.140, the public or interested organizations may submit written statements to the membership of the Panel at any time or in response to the stated agenda of a planned meeting. Written statements should be submitted to the Panel's Designated Federal Officer (DFO). The DFO's contact information can be obtained from the General Services Administration's Federal Advisory Committee Act Database at *http://facadatabase.gov/.* Written statements that do not pertain to the scheduled meeting of the Panel may be submitted at any time. However, if individual comments pertain to a specific topic being discussed at a planned meeting, then these statements must be submitted no later than 5 business days prior to the meeting in question. The DFO will review all submitted written statements and provide copies to all the committee members.

Public Comments: In addition to written statements, the Panel will set aside 1 hour for individuals or interested groups to address the Panel. To ensure consideration of their comments, individuals and interested groups should submit written statements as outlined in this notice; but if they still want to address the Panel, then they will be afforded the opportunity to register to address the Panel. The Panel's DFO will have a ''Sign-Up Roster'' available at the Panel meeting for registration on a first-come, first-serve basis. Those wishing to address the Panel will be given no more than 5 minutes to present their comments, and at the end of the 1-hour time period, no further public comments will be accepted. Anyone who signs-up to address the Panel, but is unable to do so due to the time limitation, may submit their comments in writing; however, they must understand that their written comments may not be reviewed prior to the Panel's deliberation.

To ensure timeliness of comments for the official record, the Panel encourages that individuals and interested groups consider submitting written statements instead of addressing the Panel.

Dated: November 25, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–28219 Filed 11–28–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Proposed Agency Information Collection

AGENCY: U.S. Department of Energy.

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE) invites public comment on a proposed collection of information that DOE is developing for submission to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995. This proposed information collection is in support of a new voluntary partnership program being developed by the Department aimed at making the nation's energy

system more resilient to extreme weather and climate change. 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 January 30, 2015. If you anticipate difficulty in submitting comments within that period, contact the person listed in **ADDRESSES** as soon as possible.

ADDRESSES: Written comments may be sent to Dr. Craig Zamuda, U.S. Department of Energy, EPSA–20, and 1000 Independence Avenue SW., Washington, DC 20585 or by fax 202 586–5345 or by email at *craig.zamuda@hq.doe.gov*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Dr. Craig Zamuda, U.S. Department of Energy, EPSA–20, and 1000 Independence Avenue SW., Washington, DC 20585 or by email at *craig.zamuda@hq.doe.gov*

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) OMB No. New; (2) Information Collection Request Title: Partnership for Energy Sector Climate Resilience; (3) Type of Request: New; (4) Purpose: To enhance the resilience of the nation's power sector to extreme weather and climate change, the Department of Energy is moving forward to establish a new voluntary partnership program with power sector companies. On an annual basis, companies that join the Partnership for Energy Sector Climate Resilience are asked to provide a high-level summary report on climate resilience activities pursued, milestones accomplished, and progress in enhanced energy infrastructure climate resilience. The information covered by this request will help to inform the Department about progress being made to enhance resilience. This information will also assist the Department in identifying best practices and areas where barriers to further progress exist. The information provided will enable the Department to better direct resources to those aspects of resilience planning most critical to the needs of the power sector; (5) Annual Estimated Number of Respondents; 25 (6) Annual Estimated Number of Total Responses: 50; (7) Annual Estimated Number of Burden Hours: 212 hours; (8) Annual Estimated Reporting and Recordkeeping Cost Burden: $8,959.

Statutory Authority: The Energy Independence and Security Act of 2007; Executive Order 13514—Federal Leadership in Environmental, Energy, and Economic Performance; Executive Order 13653—Preparing the United States for the Impacts of Climate Change; and the President's Climate Action Plan.

Issued in Washington, DC on November 24, 2014.

Judith M. Greenwald,

Deputy Director, Office of Climate, Environment and Efficiency, Office of Energy Policy and Systems Analysis, U.S. Department of Energy.

[FR Doc. 2014–28209 Filed 11–28–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

DOE Response to Recommendation 2014–1 of the Defense Nuclear Facilities Safety Board, Emergency Preparedness and Response

AGENCY: Department of Energy.

ACTION: Notice.

SUMMARY: On September 3, 2014, the Defense Nuclear Facilities Safety Board submitted Recommendation 2014–1, concerning *Emergency Preparedness and Response,* to the Department of Energy. In accordance with section 315(c) of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2286d(c), the following represents the Secretary of Energy's response to the Recommendation.

DATES: Comments, data, views, or arguments concerning the Secretary's response are due on or before December 31, 2014.

ADDRESSES: Please send comments to: Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW., Suite 700, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Mr. Daniel Sigg, Office of the Departmental Representative to the Defense Nuclear Facilities Safety Board, Office of Environment, Health, Safety and Security, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585, 202–586–1857.

Issued in Washington, DC on November 7, 2014.

Joe Olencz,

Departmental Representative, to the Defense Nuclear Facilities Safety Board, Office of Environment, Health, Safety and Security.

November 7, 2014

The Honorable Peter S. Winokur
Chairman
Defense Nuclear Facilities Safety Board
625 Indiana Avenue NW, Suite 700
Washington, DC 20004

Dear Mr. Chairman:

The Department of Energy (DOE) acknowledges receipt of Defense Nuclear Facilities Safety Board (Board) Recommendation 2014–01, Emergency Preparedness and Response, issued on September 3, 2014, and published in the **Federal Register** on September 23, 2014.

The Department shares the Board's view that actions are needed to improve emergency preparedness and response capabilities at its defense nuclear facilities. As stated in my August 5, 2014, letter to you, the Department's emergency preparedness and response infrastructure, capabilities, and resources are of great importance to me and DOE's senior leadership. Recommendation 2014–01 will complement the actions that the Department has already initiated to improve emergency management. I also stated that it is the Department's responsibility to determine the requisite timeline to accomplish the actions in our Implementation Plan to address Board recommendations.

I understand the Board's enabling statute requires the Department to complete implementation of its plan within one year. I am placing a high priority on addressing the Recommendation; however, due to the complexity and broad reach of the Department's actions, we probably will not be able to complete our corrective actions within one year, in which case we will make the necessary notifications prescribed by law.

Therefore, with the exception of the ''end of 2016'' timeline, DOE accepts the remainder of sub-Recommendation 1 and all of sub-Recommendation 2.

I share your intent to improve emergency management in the Department. In developing an Implementation Plan to address each specific action of this Recommendation, the Department will expeditiously proceed with improvements, accomplishing the highest priorities within a one-year period. We will prioritize efforts and will maintain a dialogue with your staff as we move forward to address your concerns.

We appreciate the Board's perspective and look forward to continued positive

interactions with you and your staff on preparing DOE's Implementation Plan. I have assigned Ms. Deborah Wilber, the Acting Associate Administrator, Office of Emergency Operations, to be the Department's responsible manager for this Recommendation.

If you have any questions, please contact me or Ms. Wilber at (202) 586–9892.

Sincerely,

Ernest J. Moniz

[FR Doc. 2014–28210 Filed 11–28–14; 8:45 am]

BILLING CODE 6450–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0222]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 30, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0222.

Title: Section 97.213, Telecommand of an Amateur Station.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for profit entities.

Number of Respondents and Responses: 40,000 respondents and 40,000 responses.

Estimated Time per Response: 5 minutes (.084 hours).

Frequency of Response: Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is approved under 47 U.S.C. 303, 151–155, 301–609.

Total Annual Burden: 3,360 hours.

Annual Cost Burden: No cost.

Privacy Act Impact Assessment: Yes. Respondents may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of the FCC rules.

The respondents' telephone numbers are collected in the Commission's Universal Licensing System (ULS) database and are covered under the System of Records Notice (SORN), FCC/WTB–1, ''Wireless Services Licensing Records.''

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information except for respondents' telephone numbers which are not made available to the public and are covered under FCC/WTB–1, ''Wireless Services Licensing Records.''

Needs and Uses: The third party disclosure requirement contained in 47 CFR 97.213 consists of posting a photocopy of the amateur station license, a label with the name, address, and telephone number of the station licensee, and the name of at least one authorized control operator in a conspicuous place at the station location. This requirement is necessary so that quick resolution of any harmful interference problems can be identified and to ensure that the station is operating in accordance with the Communications Act of 1934, as amended.

This information is used by FCC personnel during inspections and investigations to determine who is responsible for the proper operation of the remotely controlled station. In the absence of this third party disclosure requirement, field inspections and investigations related to harmful interference could be severely hampered and needlessly prolonged due to inability to determine the responsible licensee.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary. Office of the Managing Director.

[FR Doc. 2014–28160 Filed 11–28–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[3060-xxxx]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to

any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before January 30, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–xxxx.

Title: Section 74.802, Low Power Auxiliary Stations Co-channel Coordination with TV Broadcast Stations.

Form No.: Not Applicable.

Type of Review: New collection.

Respondents: Individuals and households; business or other for-profit entities; not-for-profit institutions; Federal government; and state, local or tribal government.

Number of Respondents and Responses: 400 respondents and 227 responses.

Estimated Time Per Response: 1.0 hour.

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in 47 U.S.C. 151, 154, 301, 303, 307, 308, 309, 310, 316, 319, 325(b), 332, 336(f), 338, 339, 340, 399b, 403, 534, 535, 1404, 1452, and 1454.

Total Annual Burden: 227 hours.

Total Annual Cost: $56,750.00.

Privacy Act Impact Assessment: This information collection may affect individuals or households. However, the information collection consists of third-party disclosures in which the Commission has no direct involvement. Personally identifiable information (PII) is not being collected by, made available to, or made accessible by the Commission. There are no additional impacts under the Privacy Act.

Nature and Extent of Confidentiality: In general there is no need for confidentiality with this collection of information.

Needs and Uses: On June 2, 2014, the Commission released a Report and Order, FCC 14–50, GN Docket No. 12–268, ''Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions.'' This order adopted a revision to a Commission rule, 47 CFR 74.802(b), to permit low power auxiliary stations (LPAS), including wireless microphones, to operate in the bands allocated for TV broadcasting at revised distances from a co-channel television's contour, and provided LPAS operators to operate even closer to television stations proved that any such operations are coordinated with TV broadcast stations that could be affected by the LPAS operations.

The Commission seeks Office of Management and Budget (OMB) approval for a new information collection for the coordination process adopted in the Commission's Report and Order, FCC 14–50 for such co-channel operations, in 47 CFR 74.802d(b)(2).

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2014–28158 Filed 11–28–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before December 31, 2014. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or via Internet at *Nicholas_A._Fraser@omb.eop.gov* and to Benish Shah, Federal Communications Commission, via the Internet at *Benish.Shah@fcc.gov*. To submit your PRA comments by email send them to: *PRA@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Benish Shah, Office of Managing Director, (202) 418–7866.

SUPPLEMENTARY INFORMATION: *OMB Control Number:* 3060–1116.

Title: Submarine Cable Reporting.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions.

Number of Respondents: 61 respondents; 61 responses.

Estimated Time per Response: 190 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Voluntary. Statutory authority for this information collection is contained in 47 U.S.C. §§ 151, 154(i), 154(j), 303(r) and 403.

Total Annual Burden: 11,590 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: Information provided pursuant to this request will be viewed as presumptively confidential upon submission because the information would reflect reports on weaknesses in or damage to national communications infrastructure, and the release of this sensitive information to the public could potentially facilitate terrorist targeting of critical infrastructure and key resources. The submissions also may contain internal

confidential information that constitutes trade secrets and commercial/financial information that the respondent does not routinely make public and public release of the submitted information could cause competitive harm by revealing information about the types and deployment of cable equipment and the traffic that flows across the system. For these reasons, the information requested in (b) (Terrestrial Route Map) and (c) (Undersea Location Spreadsheet) above is presumptively exempt from public disclosure under Freedom of Information Act (FOIA) Exemption 3, 5 U.S.C. § 552(b)(3), and section 4(j) of the Communications Act of 1934, as amended, 47 U.S.C. § 154(j), as implemented in 47 CFR § 0.457(c)(1)(i) (exempting disclosure of ''maps showing the exact location of submarine cables''). The information requested in (a) (System Status and Restoration Messages) and (d) (Restoration Capability) described above will be considered exempt under Exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. § 552(b)(4). If a FOIA request is filed for information submitted in response to this request, the respondent whose records are the subject of the request will be notified of the FOIA request and given the opportunity to oppose release of the records. See 47 CFR § 0.461(d)(3). We note that the information provided in response to this request will be shared with the Department of Homeland Security's National Communications System (NCS) and relevant Executive Branch agencies on a confidential basis. See 44 U.S.C. § 3510.

Needs and Uses: This information is needed in order to support Federal government national security and emergency preparedness communications programs, for the purposes of providing situational awareness of submarine cable system performance as well as a greater understanding of potential physical threats to the submarine cable systems. This information will provide situational awareness regarding the operational status of submarine cable systems to the Federal government, and allow the Executive Branch to assess potential risks and threats to these critical communications systems in the context of other available information.

Federal Communications Commission.

Gloria J. Miles,

Federal Liaison Officer.

[FR Doc. 2014–28211 Filed 11–28–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Meeting

November 26, 2014.

TIME AND DATE: 10:00 a.m., Thursday, December 11, 2014.

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW., Washington, DC 20004 (enter from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *Secretary of Labor* v. *Excel Mining, LLC,* Docket No. KENT 2009–1368. (Issues include whether the Administrative Law Judge erred by affirming a ''significant and substantial'' designation and an ''unwarrantable failure to comply'' designation.) Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFORMATION: Emogene Johnson (202) 434–9935/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll-free.

Sarah L. Stewart,

Deputy General Counsel.

[FR Doc. 2014–28371 Filed 11–26–14; 4:15 pm]

BILLING CODE 6735–01–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 December 12, 2014.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *The W. W. Pete Archbold Trust, and Michael G. Lewis as trustee of the W. W. Pete Archbold Trust,* both of Ossian, Indiana; to acquire voting shares of Ossian Financial Services, Inc., and thereby indirectly acquire voting shares of Ossian State Bank, both in Ossian, Indiana.

Board of Governors of the Federal Reserve System, November 24, 2014.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2014–28142 Filed 11–28–14; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 15, 2014.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Central Bank Corporation,* through its wholly-owned subsidiary, Central Savings Bank, and indirectly through its subsidiary Central Financial Corporation, all in Sault Sainte Marie, Michigan; to acquire no more than 20 percent of the voting shares of Lasco Development Corporation, Marquette Michigan, and thereby engage in data

processing for financial institutions, pursuant to section 225.28(b)(1).

Board of Governors of the Federal Reserve System, November 25, 2014.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2014–28213 Filed 11–28–14; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: HHS–0990–0263–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary for Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary, Department of Health and Human Services (HHS), announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0990–0263, which expires on March 31, 2015. Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before January 30, 2015.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier 0990–0263 for reference.

Information Collection Request Title: Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form—Extension OMB No. 0990–0263, Assistant Secretary for Health, Office for Human Research Protections.

OMB No.: 0990–0263

Abstract: The Office for Human Research Protections is requesting a three year extension of the Protection of Human Subjects: Assurance Identification/IRB Certification/ Declaration of Exemption Form. That form is designed to promote uniformity among departments and agencies, and to help ensure common means of ascertaining institutional review board certifications and other reporting requirements relating to the protection of human subjects in research. The Federal Policy for the Protection of Human Subjects, known as the Common Rule, requires that before engaging in non-exempt human subjects research that is conducted or supported by a Common Rule department or agency, each institution must: (1) Hold an applicable assurance of compliance [Section 103(a)]; and (2) certify to the awarding department or agency that the application or proposal for research has been reviewed and approved by an IRB designated in the assurance [Sections 103(b) and (f)].

Need and Proposed Use of the Information: The information collected through the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form is the minimum necessary to satisfy the assurance and certification requirements of Section 491 (a) of the Public Health Service Act and HHS Regulations for the protection of human subjects at 45 CFR 46.103.

Likely Respondents: Research institutions engaged in HHS-conducted or -supported research involving human subjects. Institutional use of the form is also relied upon by other federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule).

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Protection of Human Subjects: Assurance Identification/IRB Certification/ Declaration of Exemption	12,000	2	30/60	12,000
Total				12,000

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–28194 Filed 11–28–14; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–15–15FR]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted 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 notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) 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; (b) 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; (c) Enhance the quality, utility, and clarity of the information to be

collected; (d) 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; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov*. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: 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

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery—NEW—Centers for Disease Control and Prevention (CDC).

As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, the CDC has submitted a Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery '' to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et. seq*.).

To request additional information, please contact Leroy A. Richardson, Centers for Disease Control and Prevention, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

The Agency received no comments in response to the 60-day notice published in the **Federal Register** on April 30, 2014 (79 FR 24432).

This is a new collection of information. Respondents will be screened and selected from Individuals and Households, Businesses, Organizations, and/or State, Local or Tribal Government. Below we provide CDC's projected annualized estimate for the next three years. There is no cost to respondents other than their time. The estimated annualized burden hours for this data collection activity are 3,850.

ESTIMATED ANNUAL REPORTING BURDEN

Type of Collection	Number of respondents	Annual frequency per response	Hours per response
Online Surveys	1,500	1	30/60
Focus Groups	800	1	2
In-person Surveys	1,000	1	30/60
Usability testing	1,500	1	30/60
Customer comment cards	1,000	1	15/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–28192 Filed 11–28–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–15–0765]

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 Daniel Holcomb., 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.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of

information are encouraged. Your comments should address any of the following: (a) 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; (b) 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; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) 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; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written

Proposed Project

Fellowship Management System, OMB No. 0920–0765, expires 02/28/2015—Revision—Division of Scientific Education and Professional Development (DSEPD), Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), Office of Public Health Scientific Services (OPHSS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Scientific Education and Professional Development (DSEPD) requests an additional three years to continue CDC's use of the Fellowship Management System (FMS) for its electronic application, host site, and directory processes that allow individuals to apply to fellowships online, allow public health agencies to submit fellowship assignment proposals online, and track applicant and alumni information.

FMS was established to support making revisions to questions and instructions to accurately reflect evolving fellowship eligibility requirements, provide clarification of existing questions, and accommodate changing needs of the fellowship programs. This information collection request is a request for revisions to the current FMS. Revisions include features added that support the electronic submission (via file upload features) of transcripts and letters of recommendation in lieu of postal delivery; selected questions refined and new questions added to align with current fellowship eligibility requirements; and wordings of questions and instructions clarified in response to user feedback from current fellows, host sites, and alumni.

The mission of DSEPD is to improve health outcomes through a competent, sustainable, and empowered public health workforce. Professionals in public health, epidemiology, medicine, economics, information science, veterinary medicine, nursing, public policy, and other related professionals seek opportunities, through CDC fellowships, to broaden their knowledge, skills, and experience to improve the science and practice of public health. CDC fellows are assigned to state, tribal, local, and territorial public health agencies; federal government agencies, including CDC and HHS operational divisions, such as Centers for Medicare & Medicaid Services; and to nongovernmental organizations, including academic institutions, tribal organizations, and private public health organizations.

FMS provides an efficient and effective electronic mechanism for collecting and processing fellowship application data and fellowship host site assignment proposals; selecting qualified candidates; matching selected fellowship host site assignments with applicants; maintaining a current alumni database; generating reports; and documenting the impact of fellowships on alumni careers. FMS optimizes CDC's ability to provide continuous fellowship service delivery that builds and sustains public health capacity and helps to save lives and protect people from health threats. This proposed revision allows CDC to continue to use standardized electronic tools for streamlined collection of fellowship applications and fellowship assignment proposals, in the process collecting alumni information that will be used to document the impact of public health fellowships on career paths and on the science and practice of public health.

This request reflects a change in burden due to evolving fellowship requirements, increases in nonfederal respondents, and increases in information voluntarily submitted. The respondent types and burden hours for each data collection included in this request are limited to nonfederal applicants, alumni, and employees of public health agencies. The Preventive Medicine Residency and Fellowship (PMR/F) changed its program eligibility; applications for PMR/F are limited to only current CDC employees while host sites are limited to only nonfederal public health agencies. This request also reflects the elimination of the all data collections for two discontinued fellowships: The Public Health Prevention Service and The CDC Experience Applied Epidemiology Fellowship programs. Decreased burden associated with discontinuation of information collection from these fellowships is offset by increases in the number of respondents across all data collections, and increases in information submitted voluntarily by applicants in the past year when compared to amount of information submitted in previous years.

The annual burden table has been updated to reflect the number of respondents from non-federal fellowship applicants, public health agencies, and fellowship alumni.

There is no cost to respondents other than their time. The total estimated annual burden hours are 4,390.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Fellowship applicants	FMS Application Module	1,961	1	105/60
Fellowship alumni *	FMS Alumni Directory	1,382	1	15/60
Public Health Agency or Organization Staff	FMS Host Site Module	408	1	90/60

* Some alumni are deceased or cannot be located. Response burden assumes response from an individual responding alumnus, on average, every 3 years (which is likely an overestimate of frequency).

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–28193 Filed 11–28–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Fee Schedule for Reference Biological Standards and Biological Preparations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: General notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces that HHS/CDC has reviewed and updated its fee schedule for reference biological standards and biological preparations required by OMB Circular A–25, User Charges. This notice also announces current contact information to obtain information on the availability of these products and the fees for these products.

DATES: These fees are effective January 2, 2015.

FOR FURTHER INFORMATION CONTACT: To obtain information on the current inventory of reference biological standards and biological preparations and the current fee schedule, please contact the Division of Scientific Resources, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop C–17, Atlanta, Georgia 30329; telephone 404–639–3466. Someone will be available to answer your inquiry between 8:00 a.m. and 4:30 p.m. Eastern Time, Monday through Friday, except on Federal holidays.

SUPPLEMENTARY INFORMATION: On July 22, 2013 HHS/CDC published a Direct Final Rule (DFR) titled ''Distribution of Reference Biological Standards and Biological Preparations (78 FR 43817). In the DFR, HHS/CDC updated the agency name, location, and contact information for persons interested in obtaining reference biological standards and biological preparations.

On August 5, 2013, HHS/CDC published a General Notice (78 FR 47319) to inform the public that HHS/CDC has reviewed and updated its fee schedule per the requirements in OMB Circular A–25 (User Charges) and to provide contact information to obtain a current inventory of products and an up-to-date fee schedule of charges (see **FOR FURTHER INFORMATION CONTACT**).

OMB Circular A–25 (User Charges) requires that agencies review user charges for agency programs every two years. This review should include any adjustment to reflect changes in costs or market value. HHS/CDC has conducted a review of the fees charged for reference biological standards and biological preparations. Based on this review, some reagents are being removed from our inventory because they are obsolete. No prices have increased or decreased at this time.

HHS/CDC prepares reference biological standards and biological preparations under the authority of 42 CFR Part 7. These regulations describe how private entities may obtain reference biological standards and biological preparations from HHS/CDC and how charges for these standards and preparations are determined. Persons interested in these products should contact the Division of Scientific Resources, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop C–17, Atlanta, Georgia 30329; telephone 404–639–3466, for the current inventory and fee schedule. Due to the changing inventory of the unique biological standards or biological preparations, some of which are prepared only upon request, it is best to contact HHS/CDC to determine the availability of a particular product.

Dated: November 25, 2014.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2014–28226 Filed 11–28–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 79 FR 32739–32740, dated June 7, 2014) is amended to reflect the reorganization of the National Center for Immunization and Respiratory Diseases.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and the mission and function statements for the Immunization Services Division (CVGB) and insert the following:

Immunization Services Division (CVGB). The Immunization Services Division (ISD) protects individuals and communities from vaccine-preventable diseases through provision of federal funds and contracts to purchase and distribute vaccine, provision of technical and financial support of immunization programs, provider and public education, and evaluation and research.

Office of the Director (CVGB1). (1) Coordinates the division's program, policy, scientific activities and provides leadership for domestic programmatic activities; (2) links strategies and priorities of the primarily program-focused ISD branches with other NCIRD divisions working in the area of domestic immunizations and vaccine-preventable diseases; (3) facilitates development and ongoing implementation of vaccine coverage surveillance, health services and economic research, and program evaluation across the ISD branches; (4) interfaces with other CDC CIOs working in the area of immunizations and vaccine preventable diseases; (5) provides guidance for the protection of research subjects, OMB/PRA compliance, and scientific review and clearance of manuscripts and other written materials produced by ISD branches; (6) provides leadership for domestic adult immunizations in the ISD; (7) provides leadership across the branches with respect to linking preparedness and response elements to the overall influenza prevention and control strategy, and interfaces with other parts of CDC with this strategy; (8) represents ISD in other preparedness activities with vaccines as countermeasures; (9) in close coordination with NCIRD's Office of Policy, provides policy support to the ISD; (10) as appropriate, works through the NCIRD Office of Policy to serve as liaison to other policy offices, other government agencies, and external partners on policy, program, legislative, and budgetary issues related to ISD; (11) conducts policy analysis; (12) advises ISD leadership on policy and partnership issues and supports Center efforts in the management of Congressional and government relations; (13) manages cross-cutting policy issues within ISD and, as appropriate, with other policy offices within the Center and CDC; (14)

provides direct management oversight and execution of national vaccine supply contracts; (15) provides direct management and execution of procurement requisitions, contracts, and cooperative agreements, and performs administrative tasks related to initiating, processing, and maintaining interagency agreements; (16) provides direct management and execution of the administrative aspects of human resources across ISD, including training, and administration of policies and guidelines developed among others, by the Department of Health & Human Services, CDC Ethics Office, Office of the Chief Financial Officer, Office of Commissioned Corps Personnel, Office of Personnel Management, and Procurement and Grants Office; (17) provides direct management and execution of the coordination of office facilities, and supplies technical guidance and expertise regarding occupancy and facilities management including emergency situations; (18) provides direct and daily management and execution of the distribution, accountability, and maintenance of CDC property and equipment; and (19) provides direct and daily management and execution of domestic travel processing for federal employees, Commissioned Corps, and all CDC-invited guests.

Program Operations Branch (CVGBB). (1) Serves as CDC's primary interface with eligible immunization cooperative agreement awardees, supporting the awardees with development, implementation, assessment, and promotion of immunization-related activities with the goal of achieving and sustaining high immunization coverage level; (2) administers the Vaccines For Children (VFC) and Section 317 programs for eligible awardees; (3) provides technical assistance to awardees on program implementation, including implementation of all components of the VFC and Section 317 cooperative agreement; (4) monitors VFC and Section 317 cooperative agreement awardee performance; (5) manages immunization field staff; (6) supports efforts to assure accountability in the use of vaccines purchased with federal funding; (7) assures accountability of federal funds used to purchase vaccines; and (8) identifies and evaluates methods to improve immunization service delivery.

Vaccine Supply and Assurance Branch (CVGBC). (1) Oversees all aspects of domestic vaccine purchase and distribution; (2) manages centralized vaccine distribution contracts; (3) establishes and manages vaccine purchase contracts; (4) creates and maintains pediatric vaccine stockpiles; (5) coordinates and reviews awardee spend plans for vaccine ordering; (6) manages national vaccine supply shortages, including public vaccine allocations when needed; (7) tracks and monitors national seasonal influenza vaccine distribution; (8) conducts data analyses related to vaccine purchase and distribution; (9) provides storage and handling technical assistance; (10) provides awardee support and conducts planning and testing in Vaccine Tracking System (VTrckS); and (11) develops VFC program resolutions for the Advisory Committee on Immunization Practices (ACIP).

Immunization Information Systems Support Branch (CVGBE). (1) Supports the CDC vision of ''A nation without vaccine-preventable disease, disability, and death'' by making high quality data from immunization information systems (ITS) available to clinical, administrative, public health, and other immunization stakeholders; (2) provides leadership, operational, technical and resource support to develop a nationwide network of fully operational and integrated IIS and other health systems; (3) ensures high-quality IIS data and system functionality by identifying, developing, implementing, promoting, and evaluating standards and best practices; (4) promotes the effective use of IIS data and system functions to support vaccination providers, public health programs, other immunization stakeholders, and policy needs; (5) monitors, evaluates, and reports emerging industry and environmental trends that influence IIS operations; and (6) supports the exchange of information about IIS and collaborative efforts to advance ITS operations with partners.

Assessment Branch (CVGBG). (1) Lead domestic vaccination coverage assessment across the lifespan; (2) assess the impact of interventions, policies and disseminating and promoting use of this information to improve vaccination coverage; (3) conducts assessment of vaccination coverage, related health services, and other factors associated with vaccination across the lifespan; (4) conducts and manages the National Immunization Survey (NIS) to assess vaccination coverage and related information among children aged 19–35 months and 13–17 years, and as needed, other age groups; (5) collects, analyzes, and disseminates accurate and timely vaccination coverage and related information using the NIS and other survey mechanisms and clinical data sources; (6) assists national, state and local immunization programs in collection, analysis, interpretation, and use of vaccination coverage assessment and evaluation information to guide policy and program activities; (7) conducts research and evaluations to assess and reduce racial/ethnic and other disparities in vaccination, evaluate impact of interventions, policies, and program activities on vaccination coverage, and measure disease and economic impact of specific interventions and vaccination programs; and (8) conducts research to evaluate and improve the validity and cost-effectiveness of NIS and other assessment systems used to collect vaccination coverage data.

Communication and Education Branch (CVGBH). (1) Works through communications and educational efforts to improve knowledge and influence changes in behavior of domestic health care providers and the general public to reduce vaccine-preventable diseases across the life span; (2) collaborate with NCIRD Health Communication Science Office (HCSO) to develop communications strategies and provide communications and media support for ISD; (3) develops and disseminates domestic immunization messages, materials, and educational offerings for health care providers and consumers related to ISD's scientific and programmatic work; (4) supports the CDC immunization response system; (5) collaborates with national immunization partner groups to achieve programmatic goals; (6) through NCIRD HCSO provides technical assistance for national immunization communications campaigns; (7) provides Continuing Education credits for immunization-related education and training products; and (8) participates on the ACIP work groups and develops and promotes ACIP schedules and recommendations.

Dated: October 29, 2014.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2014–28220 Filed 11–28–14; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1030]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Allergen Labeling and Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 31, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Food Allergen Labeling and Reporting''. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Food and Drug Administration, 8455 Colesville Road, COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Allergen Labeling and Reporting—(OMB Control Number 0910–NEW)

I. Background

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II, Pub. L. 108–282) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by defining the term ''major food allergen'' and stating that foods regulated under the FD&C Act are misbranded unless they declare the presence of each major food allergen on the product label using the name of the food source from which the major food allergen is derived. Section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)) sets forth the requirements for declaring the presence of each major food allergen on the product label. Section 201(qq) of the FD&C Act (21 U.S.C. 321(qq)) defines a major food allergen as ''[m]ilk, egg, fish (*e.g.,* bass, flounder, or cod), Crustacean shellfish (*e.g.,* crab, lobster, or shrimp), tree nuts (*e.g.,* almonds, pecans, or walnuts), wheat, peanuts, and soybeans'' and also as a food ingredient that contains protein derived from such foods. The definition excludes any highly refined oil derived from a major food allergen and any ingredient derived from such highly refined oil.

In some cases, the production of an ingredient derived from a major food allergen may alter or eliminate the allergenic proteins in that derived ingredient to such an extent that it does not contain allergenic protein. In addition, a major food allergen may be used as an ingredient or as a component of an ingredient such that the level of allergenic protein in finished food products does not cause an allergic response that poses a risk to human health. Therefore, FALCPA provides two mechanisms through which such ingredients may become exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. An ingredient may obtain an exemption through submission and approval of a petition containing scientific evidence that demonstrates that the ingredient ''does not cause an allergic response that poses a risk to human health'' (section 403(w)(6) of the FD&C Act (21 U.S.C. 343(w)(6)). Alternately, an ingredient may become exempt through submission of a notification containing scientific evidence showing that the ingredient ''does not contain allergenic protein'' or that there has been a previous determination through a premarket approval process under section 409 of the FD&C Act (21 U.S.C. 348) that the ingredient ''does not cause an allergic response that poses a risk to human health'' (section 403(w)(7) of the FD&C Act (21 U.S.C. 343(w)(7)).

In the **Federal Register** of May 8, 2014 (79 FR 26435), we published a notice of availability for the draft guidance document entitled, ''Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications.'' This draft guidance is intended to help industry prepare petitions and notifications seeking exemptions from the labeling requirements for ingredients derived from major food allergens. Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/FoodGuidances.*

II. Analysis of the Proposed Information Collection

The proposed information collection seeks OMB approval of the third party disclosure requirements of food allergen labeling under section 403(w)(1) of the FD&C Act, as well as OMB approval of the reporting associated with the submission of petitions and notifications seeking exemptions from the labeling requirements for ingredients derived from major food allergens under section 403(w)(6) and (7) of the FD&C Act.

A. Third Party Disclosure

The labeling requirements of section 403(w)(1) of the FD&C Act apply to all packaged foods sold in the United States that are regulated under the FD&C Act, including both domestically manufactured and imported foods. As noted, section 403(w)(1) of the FD&C Act requires that the label of a food product declare the presence of each major food allergen. We estimate the information collection burden of the third party disclosure associated with food allergen labeling under section 403(w)(1) of the FD&C Act as the time needed for a manufacturer to review the labels of new or reformulated products for compliance with the requirements of section 403(w)(1) of the FD&C Act and the time needed to make any needed modifications to the labels of those products.

The primary user of the allergen information disclosed on the label or labeling of food products is the consumer that purchases the food product. Consumers will use the information to help them make choices concerning their purchase of a food product, including choices related to substances that the consumer wishes to avoid due to their potential to cause adverse reactions. Additionally, we intend to use the information to determine whether a manufacturer or other supplier of food products is meeting its statutory obligations. Failure of a manufacturer or other supplier of food products to label its products in compliance with section 403(w)(1) of the FD&C Act may result in a product being misbranded under the FD&C Act and the manufacturer or packer and the product subject to regulatory action.

Description of respondents: The respondents to this collection of information are manufacturers and packers of packaged foods sold in the United States.

In the **Federal Register** of August 12, 2014 (79 FR 47145), we published a 60-day notice requesting public comment on the proposed collection of

information. Although one comment was received, it did not respond to any of the four collection of information topics solicited and therefore is not discussed in this document.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN [1]

FD&C Act Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Avg. burden per disclosure	Total hours	Total capital costs
403(w)(1); review labels for compliance with food allergen labeling requirements	77,500	1	77,500	1	77,500	0
403(w)(1); redesign labels to comply with food allergen labeling requirements	3,875	1	3,875	16	62,000	$7,071,875
Total					139,500	$7,071,875

[1] There are no operating and maintenance costs associated with this collection of information.

We used our labeling cost model (Ref. 1) to estimate the number of new or reformulated products sold in the United States, annually, that are affected by the requirements of section 403(w)(1) of the FD&C Act. We estimate that there are approximately 690,000 Universal Product Codes (UPCs) of FDA-regulated foods and approximately 85,000 UPCs of FDA-regulated dietary supplements for a total of 775,000 UPCs (Ref. 1). Using our labeling cost model, we estimate the entry rate of new UPCs to be approximately 8 percent per year. Based on the approximate entry rate of new UPCs, we estimate the rate of new or reformulated UPCs to be approximately 10 percent per year, or 77,500 products (775,000 × 10 percent). Thus, we estimate that, annually, 77,500 new or reformulated products are sold in the United States. Assuming an association of one respondent to each of the 77,500 new or reformulated products, we estimate that 77,500 respondents will each review the label of one of the 77,500 new or reformulated products, as reported in table 1, row 1. We have no data on how many label reviews would identify the need to redesign the label. Therefore, we further estimate, for the purposes of this analysis, that 5 percent of the reviewed labels of new or reformulated products, or 3,875 labels (77,500 × 5 percent) would need to be redesigned to comply with the requirements of section 403(w)(1) of the FD&C Act. Assuming an association of one respondent to each of the 3,875 labels, we estimate that 3,875 respondents will each redesign one label, as reported in table 1, row 2.

Our estimate of the average burdens per disclosure reported in table 1 is based on our experience with food labeling and our labeling cost model. We estimate the average burden for the review of labels for compliance with the food allergen labeling requirements under section 403(w)(1) of the FD&C Act to be 1 hour. Consequently, the burden of reviewing the labels of new or reformulated products is 77,500 hours, as reported in table 1. Using our labeling cost model, we estimate that it takes an average of 16 hours to complete the administration and internal design work for the redesign of a label to comply with the food allergen labeling requirements under section 403(w)(1) of the FD&C Act. Consequently, the burden of redesigning the 3,875 labels of new or reformulated products is 62,000 hours, as reported in table 1.

Using our labeling cost model, we estimate the capital cost to be $1,825 per label for external design services for the redesign of a label. Consequently for 3,875 labels, the total capital costs are $7,071,875 (3,875 labels × $1,825 per label), as reported in table 1.

B. Reporting

Under sections 403(w)(6) and (7) of the FD&C Act, interested parties may request from us a determination that an ingredient is exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. An ingredient may obtain an exemption through submission and approval of a petition containing scientific evidence that demonstrates that the ingredient ''does not cause an allergic response that poses a risk to human health'' (section 403(w)(6) of the FD&C Act). This section also states that ''the burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.'' Alternately, an ingredient may become exempt through submission of a notification containing scientific evidence showing that the ingredient ''does not contain allergenic protein'' or that there has been a previous determination through a premarket approval process under section 409 of the FD&C Act that the ingredient ''does not cause an allergic response that poses a risk to human health'' (section 403(w)(7) of the FD&C Act).

Our draft guidance document entitled, ''Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications,'' sets forth our recommendations with regard to the information that an interested party should submit in such a petition or notification. The draft guidance states that to evaluate these petitions and notifications, we will consider scientific evidence that describes:

1. The identity or composition of the ingredient;

2. The methods used to produce the ingredient;

3. The methods used to characterize the ingredient;

4. The intended use of the ingredient in food; and either

5. a. For a petition, data and information, including the expected level of consumer exposure to the ingredient, that demonstrate that the ingredient when manufactured and used as described does not cause an allergic response that poses a risk to human health; or

5. b. For a notification, data and information that demonstrate that the ingredient when manufactured as described does not contain allergenic protein, or documentation of a previous determination under a process under section 409 of the FD&C Act that the ingredient does not cause an allergic response that poses a risk to human health.

We will use the information submitted in the petition or notification to determine whether the ingredient satisfies the criteria of sections 403(w)(6) and (7) of the FD&C Act for granting the exemption.

Description of respondents: The respondents to this collection of information are manufacturers and packers of packaged foods sold in the

United States that seek an exemption from the labeling requirement of section 403(w)(1) of the FD&C Act.

We estimate the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
403(w)(6); petition for exemption	5	1	5	100	500
403(w)(7); notification	5	1	5	68	340
Total					840

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on the number of petitions and notifications received in recent years, we estimate that we will receive an average of five petitions and five notifications annually, over the next 3 years. Assuming an association of one respondent to each petition or notification, we estimate that five respondents will each submit one petition, and five respondents will each submit one notification, as reported in table 2, rows 1 and 2.

We base our estimate of the average burdens per response reported in table 2 on our experience with other petition processes. We estimate that a petition would take, on average, 100 hours to develop and submit (Ref. 2). Therefore, we estimate that the burden associated with petitions will be 500 hours annually (5 petitions $\times$ 100 hours per petition).

The burden of a notification involves collecting documentation that a food ingredient does not pose an allergen risk. Either we can make a determination that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 409 of the FD&C Act, or the respondent would submit scientific evidence demonstrating that the ingredient, when manufactured as described, does not contain allergenic protein. We estimate that it would take a respondent 20 hours to prepare and submit a notification based on our determination under a process under section 409 of the FD&C Act that the ingredient does not cause an allergic response. We estimate that it would take a respondent approximately 100 hours to prepare a notification submitting scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein. We have no data on how many notifications would be based on our determination that the ingredient does not cause an allergic response or based on scientific evidence that demonstrates that the food ingredient does not contain allergenic protein. Therefore, we estimate that three of the five notifications would be based on scientific evidence, and two of the five notifications would be based on our determination. The average time per notification is then estimated to be 68 hours (2×20 hours $+3 \times 100$ hours)/5). Therefore, we estimate that the burden associated with notifications will be 340 hours annually (5 notifications $\times$ 68 hours per notification), as reported in table 2.

III. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. RTI International. ''Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration, Final Report.'' Prepared for Andrew Stivers, FDA/CFSAN. Prepared by Muth, M., M. Ball, M. Coglaiti, and S. Karns. RTI Project Number 0211460.005. March, 2011.
2. Gendel, Steven M. ''Food Allergen Petitions and Notifications,'' Memorandum to File. August 8, 2011.

Dated: November 24, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28185 Filed 11–28–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0639]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Notification of the Intent To Use an Accredited Person Under the Accredited Persons Inspection Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 31, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0569. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Notification of the Intent To Use an Accredited Person Under the Accredited Persons Inspection Program (Formerly Requests for Inspection Under the Inspection by Accredited Persons Program)—(OMB Control Number 0910–0569)—Extension

Section 201 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) amended section 704 of the Federal Food, Drug, and Cosmetic Act by adding subsection (g) (21 U.S.C. 374(g)). This amendment authorized FDA to establish a voluntary third-party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. In 2007, the program was modified by the Food and Drug Administration Amendments Act of 2007 by revising eligibility criteria and by no longer requiring prior approval by FDA. To reflect the revisions, FDA modified the title of the collection of information and on March 2, 2009, issued a guidance entitled ''Manufacturer's Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007.'' This guidance supersedes the Agency's previous guidance regarding requests for third-party inspection and may be found on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085187.htm.* This guidance is intended to assist device establishments in determining whether they are eligible to participate in the Accredited Person (AP) Program and, if so, how to submit notification of their intent to use the program. The AP Program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such manufacturers may need current inspections of their establishments to operate in global commerce.

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP Program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible to participate in the AP Program. Further, 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP Program. Based on communications with industry, FDA estimates that on an annual basis approximately 20 of these manufacturers may use an AP in any given year.

In the **Federal Register** of May 28, 2014 (79 FR 30619), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 U.S.C. section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification regarding use of an accredited person—374(g)	20	1	20	15	300

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 24, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28184 Filed 11–28–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0619]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Humanitarian Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 31, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0332. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Humanitarian Use Devices—21 CFR 814 (OMB Control Number 0910–0332)—Extension

This collection of information implements the Humanitarian Use Devices (HUD) provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m)) and subpart H, part 814 (21 CFR part 814). Under section 520(m) of the FD&C Act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless an exemption is granted because there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose the disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury with the probable benefit to health from using the device outweighing the risk of injury or illness from its use. This takes

into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

The number of respondents in tables 1, 2, and 3 of this document are an average based on data for the previous 3 years, *i.e.,* fiscal years 2011 through 2013. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects 32 respondents with approved HUD applications. Likewise, under § 814.126(b)(2) in table 2, the number of recordkeepers is 247.

In the **Federal Register** of June 10, 2014 (79 FR 33197), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for HUD designation—814.102	16	1	16	40	640
Humanitarian device exemption (HDE) application—814.104	7	1	7	320	2,240
HDE amendments and resubmitted HDEs—814.106	14	5	70	50	3,500
HDE supplements—814.108	112	1	112	80	8,960
Notification of withdrawal of an HDE—814.116(e)(3)	8	1	8	1	8
Notification of withdrawal of institutional review board approval—814.124(b)	3	1	3	2	6
Periodic reports—814.126(b)(1)	32	1	32	120	3,840
Total					19,194

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeping	Total annual records	Average burden per recordkeeping	Total hours
HDE Records—814.126(b)(2)	247	1	247	2	494

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 24, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28183 Filed 11–28–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1952]

Seventh Annual Sentinel Initiative; Public Workshop; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; amendment of notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of a public workshop entitled ''Seventh Annual Sentinel Initiative'' to be held on February 5, 2015. The workshop was announced in the **Federal Register** of October 22, 2014. This amendment reflects the addition of a *Comments* section and updates an incorrect Web site in the *Meeting Materials* section.

FOR FURTHER INFORMATION CONTACT: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6358, Silver Spring, MD 20993, 301–796–3714, FAX: 301–847–3529, email: *SentinelInitiative@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

In the **Federal Register** of October 22, 2014 (79 FR 63130), FDA announced that a public workshop entitled ''Seventh Annual Sentinel Initiative'' will be held on February 5, 2015.

1. On page 63131, in the second column, in the sixth line of the *Meeting Materials* section, the Web site ''*http://www.brookings.edu//health/events*'' is changed to read ''*http://www.brookings.edu/events*''.

2. On page 63131, in the second column, a *Comments* section is added between the *Meeting Materials* section and the *Transcripts* section to read:

''*Comments:* FDA is holding this public workshop to obtain information about a variety of topics on active medical product surveillance. The deadline for submitting comments regarding this public workshop is March 10, 2015.

Regardless of attendance in person or through the Web cast, interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and

will be posted to the docket at *http://www.regulations.gov.*''

Dated: November 20, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28196 Filed 11–28–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Eye Council.

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 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/or 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 grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Eye Council

Date: January 22, 2015.

Open: 8:30 a.m. to 2:00 p.m.

Agenda: Following opening remarks by the Director, NEI, there will be presentations by the staff of the Institute and discussions concerning Institute programs.

Place: National Institutes of Health, Terrace Level Conference Rooms, 5635 Fishers Lane, Bethesda, MD 20892.

Closed: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Terrace Level Conference Rooms, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Anne E Schaffner, Ph.D., Chief, Scientific Review Branch, Division of Extramural Research National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, Bethesda, MD 20892–9300, (301) 451–2020.

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.

Information is also available on the Institute's/Center's home page: *www.nei.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: November 24, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–28165 Filed 11–28–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2014–0074]

Privacy Act of 1974; Department of Homeland Security U.S. Immigration and Customs Enforcement–005 Trade Transparency Analysis and Research (TTAR) System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to update and reissue a current Department of Homeland Security system of records titled, ''Department of Homeland Security/Immigration and Customs Enforcement–005 Trade Transparency Analysis and Research (TTAR) System of Records.'' This system of records is being modified to (1) update existing and include new categories of individuals, (2) clarify existing and include new categories of records, (3) reflect a proposed change to the retention period of the system's data, and (4) update the description of the record sources. In addition, the Department is notifying the public of changes triggered by the replacement of the TTAR SORN's associated IT system, the Data Analysis and Research for Trade Transparency System (DARTTS), with FALCON–DARTTS, which replicates the functionality of and serves the same user groups as legacy DARTTS. The TTAR SORN is also being updated to expand coverage to a new IT system called FALCON-Roadrunner. The FALCON–DARTTS and FALCON-Roadrunner Privacy Impact Assessments are posted on the Department privacy Web site (*see www.dhs.gov/privacy*). The exemptions for the existing system of records notice will continue to be applicable for this system of records notice. This updated system will be included in the Department of Homeland Security's inventory of record systems.

DATES: Submit comments on or before December 31, 2014. This updated system will be effective December 31, 2014.

ADDRESSES: You may submit comments, identified by docket number DHS–2014–0074 by one of the following methods:

- Federal e-Rulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Fax: 202–343–4010.
- Mail: Karen L. Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Lyn Rahilly, Privacy Officer, U.S. Immigration and Customs Enforcement, 500 12th Street SW., Mail Stop 5004, Washington, DC 20536, phone: 202–732–3300, email: *ICEPrivacy@dhs.gov.* For privacy questions, please contact: Karen Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528, phone: 202–343–1717.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) U.S. Immigration and Customs Enforcement (ICE) proposes to update and reissue a current DHS system of records titled ''DHS/ICE–005 Trade Transparency Analysis and Research (TTAR) System of Records.'' This system allows ICE Homeland Security Investigations (HSI) to collect and maintain records for the purpose of enforcing criminal and civil laws pertaining to customs violations, including trade-based money laundering. With this update, ICE is notifying the public of changes triggered by the replacement of the TTAR SORN's

associated IT system, the Data Analysis and Research for Trade Transparency System (DARTTS), with FALCON–DARTTS, which replicates the functionality of and serves the same user groups as legacy DARTTS. The TTAR SORN is also being updated to expand coverage to a new ICE IT system, FALCON-Roadrunner.

The FALCON Environment

In 2012, HSI created a new IT environment called ''FALCON'' to support its law enforcement and criminal investigative mission. The FALCON environment is designed to permit ICE law enforcement and homeland security personnel to search and analyze data ingested from other government applications and systems, with appropriate user access restrictions at the data element level and robust user auditing controls. FALCON modules, such as FALCON–DARTTS and FALCON-Roadrunner, have been deployed in support of discrete HSI mission areas and work units.

Data analyzed by the FALCON modules is aggregated and stored in the FALCON general data storage environment. The data stored in this environment is ingested on a routine or *ad hoc* basis from other existing sources and is structured and optimized for use with the analytical tools in FALCON–DARTTS, FALCON-Roadrunner, and the other FALCON modules. For more information on the FALCON environment, please see the FALCON-Search and Analysis PIA at *www.dhs.gov/privacy.*

FALCON–DARTTS

As described above, in January 2014, ICE migrated the DARTTS system to the HSI FALCON environment and launched FALCON–DARTTS. FALCON–DARTTS replicates the functionality of and serves the same user groups as the legacy DARTTS system. The purpose of FALCON–DARTTS is to allow HSI investigators to generate leads for, and otherwise support, investigations of trade-based money laundering, smuggling, commercial fraud, and other crimes within the jurisdiction of HSI. FALCON–DARTTS analyzes trade and financial data to identify statistically anomalous transactions that may warrant investigation. These anomalies are then independently confirmed and further investigated by HSI investigators. With the deployment of FALCON–DARTTS, the legacy DARTTS system (which included a component called ''Foreign DARTTS'' used by HSI's foreign law enforcement and customs partners) was retired.

ICE published a new PIA for FALCON–DARTTS on January 16, 2014, to address the migration from legacy DARTTS and to notify the public of several new system features, including (1) additional datasets and records and (2) an updated way in which datasets are physically separated. First, ICE has added to FALCON–DARTTS new financial data as well as records manually uploaded on an *ad hoc* basis, which may include financial records, business records, trade transaction records, and transportation records.

Second, financial and law enforcement datasets analyzed by FALCON–DARTTS are maintained in the FALCON general data storage environment. In this environment, the data is aggregated with other FALCON data, and user access is controlled through a combination of data tagging, access control lists, and other technologies. Trade data (*i.e.,* data relating to the importation and exportation of merchandise) is maintained separately in the FALCON–DARTTS trade data subsystem, which is physically and logically separate from the FALCON general data storage environment and contains different user access requirements, including requirements that export data only be used for enforcement actions involving cargo safety and security or to prevent smuggling, than the overarching FALCON–SA data storage environment. All FALCON–DARTTS users, including select foreign law enforcement and customs officials who have access to the system, access trade data through the trade data subsystem. The PIA for FALCON–DARTTS is available at *www.dhs.gov/privacy.*

FALCON-Roadrunner

FALCON-Roadrunner is a new system that analyzes export and financial data across large, disparate trade, financial, law enforcement, and other commercially- and publicly-available datasets. The system creates and automatically applies repeatable, analytical queries and processes to determine non-obvious, anomalous behaviors, patterns, and relationships within and across the large-scale datasets. These anomalies, patterns, and relationships provide leads that may warrant investigation for violation of U.S. export laws and regulations. Once identified, anomalies are then independently confirmed and further investigated by HSI investigators.

FALCON-Roadrunner also supports HSI by providing export enforcement-related statistical reporting capabilities, derived from trade and financial data. These statistical functions discern, describe, and document trends within the datasets associated with proliferation, export licensing, and other export enforcement trends in order to inform ICE decision makers. The PIA for FALCON-Roadrunner is being published concurrently with this update to the DHS/ICE–005 TTAR System of Records and is available at *www.dhs.gov/privacy.*

Changes to Categories of Individuals, Categories of Records, Retention, and Record Sources

With the migration of DARTTS to FALCON–DARTTS and the deployment of FALCON-Roadrunner, the TTAR system of records is being modified to (1) update existing and include new categories of individuals; (2) clarify existing and include new categories of records; (3) reflect a proposed change to the retention period of the data; and (4) update the description of the record sources.

Existing categories of individuals in the DHS/ICE–005 TTAR SORN have been updated to include additional individuals. Individuals whose financial records have been lawfully obtained by law enforcement agencies during official investigations, legal processes, and/or legal settlements have been added to category (2) below; individuals identified on other denied parties or screening lists have been added to category (3) below; and individuals identified in TECS investigative records have been added to category (4) below. In addition, a new category of individuals has been added to cover applicants for U.S. visas and other individuals identified on visa applications.

Existing categories of records have been updated to clarify and simplify the description of records. Previously categorized as ''customs, trade, and financial data,'' these records are now described separately as ''trade data'' and ''financial data.'' In addition, new law enforcement records have been added, including TECS investigative records, visa security information, and trade-based and financial sanction screening lists.

The retention period for data maintained under the TTAR system of records is also being updated. Previously, data was maintained in the legacy DARTTS system for five years, archived for an additional five years, and then deleted. ICE intends to request National Archives and Records Administration (NARA) approval to retire the legacy DARTTS retention schedule. Datasets analyzed by FALCON–DARTTS and FALCON-Roadrunner will be incorporated into

the forthcoming retention schedule for the FALCON environment. ICE is proposing to retain datasets used in support of FALCON–DARTTS and FALCON-Roadrunner for ten years. Some of the data analyzed by FALCON–DARTTS and FALCON-Roadrunner is already maintained in the FALCON environment and subject to a proposed retention period there; however, FALCON–DARTTS and FALCON-Roadrunner will only access these existing datasets for ten years.

Lastly, new records sources have been added as a result of the new datasets covered by this system of records. New data sources added to this system of records includes additional federal, state, and local government agencies; companies; and commercially and publicly available datasets.

Consistent with DHS's information sharing mission, information stored in the DHS/ICE–005 TTAR System of Records may be shared with other DHS components that have a need to know the information to carry out their national security, law enforcement, immigration, intelligence, or other homeland security functions. In addition, DHS/ICE may share information with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this system of records notice.

The exemptions for the existing system of records notice will continue to be applicable for this system of records notice. This updated system will be included in DHS's inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which the federal government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals when systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

Below is the description of the amended DHS/ICE–005 Trade Transparency Analysis and Research System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM OF RECORDS:

Department of Homeland Security (DHS)/U.S. Immigration and Customs Enforcement (ICE)–005.

SYSTEM NAME:

DHS/ICE–005 Trade Transparency Analysis and Research (TTAR).

SECURITY CLASSIFICATION:

Sensitive But Unclassified, Law Enforcement Sensitive.

SYSTEM LOCATION:

Records are maintained in FALCON–DARTTS and FALCON-Roadrunner, which are IT systems owned and operated by ICE and maintained in a DHS data center. FALCON–DARTTS and FALCON-Roadrunner are accessed through the ICE Network.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include:

(1) Individuals who, as importers, exporters, shippers, transporters, customs brokers, owners, purchasers, consignees, or agents thereof, participate in the import or export of goods to or from the United States or to or from nations with which the United States has entered an agreement to share trade information;

(2) Individuals who participate in financial transactions that are reported under the Bank Secrecy Act, or that are obtained by law enforcement agencies during official investigations, legal processes, or legal settlements;

(3) Specially Designated Nationals as defined by 31 CFR 500.306 and individuals identified on other denied parties or screening lists;

(4) Individuals identified in TECS subject records and investigative records created by ICE and U.S. Customs and Border Protection (CBP), including violators or suspected violators of laws enforced or administered by ICE and CBP; witnesses associated with ICE and CBP enforcement actions; persons who own or operate businesses, property, vehicles or other property that is in a TECS subject record; and individuals applying for a license issued by DHS or for which DHS conducts a background investigation in support of the licensing agency; and

(5) U.S. visa applicants and other individuals who are identified on the visa application (*e.g.,* the applicant's spouse, individuals traveling with the applicant, application preparer's name, applicant's point of contact in the United States).

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records in this system include:

(1) Biographic and other identifying information, including names; dates of birth; places of birth; Social Security numbers (SSN); Tax Identification Numbers (TIN); Exporter Identification Numbers (EINs); passport information (number and country of issuance); citizenship; nationality; location and contact information (*e.g.,* home, business, and email addresses and telephone numbers); and other identification numbers (*e.g.,* Alien Registration Number, driver's license number).

(2) Trade data, including trade identifier numbers (*e.g.,* for manufacturers importers, exporters, and customs brokers) and bill of lading data (*e.g.,* consignee names and addresses, shipper names and addresses, container numbers, carriers).

(3) Financial data, including data reported pursuant to the Bank Secrecy Act (*e.g.,* certain transactions over $10,000) and other financial data obtained via official investigations, legal processes, or legal settlements. Financial data includes, but is not limited to, bank account numbers, transaction numbers, and descriptions or value of financial transactions.

(4) Licensing information related to applications by individuals or businesses to hold or retain a customs broker's license, or operate a customs-bonded warehouse, or be a bonded carrier or bonded cartman.

(5) Law enforcement records, including TECS subject records and investigative records related to an ICE or CBP law enforcement matter, information obtained from the U.S. Department of Treasury's Specially Designated Nationals List, visa security information, and other trade-based and financial sanction screening lists. Law enforcement data includes, but is not limited to, names; aliases; business names; addresses; dates of birth; places of birth; citizenship; nationality; passport information; SSNs; TINs; driver's license numbers; and vehicle, vessel, and aircraft information.

(6) Other financial records, business records, trade transaction records, and transportation records associated with official law enforcement purposes.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

ICE is authorized to collect this information pursuant to 6 U.S.C. 236; 19 U.S.C. 1589a; the Trade Act of 2002 § 343 (Note to 19 U.S.C. 2071); 19 U.S.C. 1484; 50 U.S.C. app. § 2411; 19 CFR 161.2 and 192.14; and, 31 U.S.C. 5316 and 31 CFR 1010.340. HSI has the jurisdiction and authority to investigate violations involving the importation and exportation of merchandise into or out of the United States. Information analyzed by FALCON–DARTTS, supports, among other things, HSI's investigations into smuggling violations under 18 U.S.C. 541, 542, 545, and 554; financial crimes investigations under 18 U.S.C. 1956, 1957, and 1960 and the Bank Secrecy Act; and merchandise imported in non-compliance with 19 U.S.C. 1481 and 1484. Information analyzed by FALCON-Roadrunner supports, among other things, HSI's investigations into export violations—particularly those involving violations under 22 U.S.C. 2778 and 50 U.S.C. 1705.

PURPOSE(S):

The purpose of this system is to support:

(1) The enforcement of criminal and civil laws pertaining to trade, financial crimes, smuggling, and fraud, and the collection of all lawfully owned revenue from trade activities, specifically through the analysis of raw financial and trade data in order to identify potential violations of U.S. criminal and civil laws pertaining to export violations, cargo safety and security, smuggling, and related violations—including financial crimes and trade-based money laundering;

(2) Existing criminal law enforcement investigations into related criminal activities and civil enforcement actions to recover revenue and assess fines and penalties;

(3) The sharing of data and analytical capabilities with foreign customs and law enforcement partners to further collaboration and cooperation between HSI and such officials as well as to support those officials' abilities to engage in enforcement activities involving cargo safety and security, smuggling, and related violations—including financial crimes and trade-based money laundering;

(4) The cooperation and collaboration between the United States and foreign government partners on investigations into transnational activities that violate criminal and civil laws pertaining to trade, financial activities, smuggling, and fraud; and

(5) The identification of potential criminal activity, immigration violations, and threats to homeland security; to uphold and enforce the law; and to ensure public safety.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including Offices of the U.S. Attorneys or other federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

(1) DHS or any component thereof;

(2) Any employee of DHS in his/her official capacity;

(3) Any employee of DHS in his/her individual capacity when DOJ or DHS has agreed to represent the employee; or

(4) The U.S. or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency, organization, or individual for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To agencies, entities, and persons when:

(1) DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

(2) DHS has determined that as a result of the suspected or confirmed compromise there is a risk of identity theft or fraud, harm to the economic or property interests, harm to an individual, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) that rely upon the compromised information; and

(3) The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, interns, trainees, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To federal, state, local, tribal, territorial, or foreign government agencies, as well as to other individuals and organizations during the course of an investigation by DHS or the processing of a matter under DHS's jurisdiction, or during a proceeding within the purview of the immigration and nationality laws, when DHS deems that such disclosure is necessary to carry out its functions and statutory mandates or to elicit information required by DHS to carry out its functions and statutory mandates.

H. To federal, state, local, tribal, territorial, or foreign government agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, license, or treaty when DHS determines that the information would assist in the enforcement of civil, criminal, or regulatory laws.

I. To federal, state, local, tribal, or territorial government agencies, or other entities or individuals, or through established liaison channels to selected foreign governments, in order to provide intelligence, counterintelligence, or other information for the purposes of national security, intelligence, counterintelligence, or antiterrorism activities authorized by U.S. law, Executive Order, or other applicable national security directive.

J. To federal, state, local, tribal, territorial, or foreign government agencies or organizations, or international organizations, lawfully engaged in collecting law enforcement intelligence, whether civil or criminal, to enable these entities to carry out their law enforcement responsibilities, including the collection of law enforcement intelligence.

K. To international, foreign, intergovernmental, and multinational government agencies, authorities, and organizations in accordance with law

and formal or informal international arrangements.

L. To federal and foreign government intelligence or counterterrorism agencies or components when DHS becomes aware of an indication of a threat or potential threat to national or international security, or when such disclosure is to support the conduct of national intelligence and security investigations or assist in antiterrorism efforts.

M. To federal, state, local, tribal, territorial, international, or foreign government agencies or multinational governmental organizations when DHS desires to exchange relevant data for the purpose of developing, testing, or implementing new software or technology whose purpose is related to the purpose of this system of records.

N. To courts, magistrates, administrative tribunals, opposing counsel, parties, and witnesses, in the course of immigration, civil, or criminal proceedings (including discovery, presentation of evidence, and settlement negotiations) before a court or adjudicative body when any of the following is a party to or have an interest in the litigation:

(1) DHS or any component thereof;

(2) any employee of DHS in his/her official capacity;

(3) any employee of DHS in his/her individual capacity when the government has agreed to represent the employee; or

(4) the United States, when DHS determines that litigation is likely to affect DHS or any of its components; and when DHS determines that use of such records is relevant and necessary to the litigation and is compatible with the purposes for which the records were collected.

O. To prospective claimants and their attorneys for the purpose of negotiating the settlement of an actual or prospective claim against DHS or its current or former employees, in advance of the initiation of formal litigation or proceedings.

P. To federal, state, local, tribal, territorial, international, or foreign government agencies or entities for the purpose of consulting with those agencies or entities:

(1) To assist in making a determination regarding redress for an individual in connection with the operations of a DHS component or program;

(2) to verify the identity of an individual seeking redress in connection with the operations of a DHS component or program; or

(3) to verify the accuracy of information submitted by an individual who has requested redress on behalf of another individual.

Q. To a former employee of DHS for the purpose of responding to an official inquiry by federal, state, local, tribal, or territorial government agencies or professional licensing authorities; or facilitating communications with a former employee that may be necessary for personnel-related matters or other official purposes when DHS requires information or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

R. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information, when disclosure is necessary to preserve confidence in the integrity of DHS, or when disclosure is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent the Chief Privacy Officer determines that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored electronically or on paper in secure facilities in a locked drawer behind a locked door. The records are stored on magnetic disc, tape, digital media, and CD–ROM.

RETRIEVABILITY:

Records may be retrieved by any of the personal identifiers stored in the system including name, business address, home address, importer ID, exporter ID, broker ID, manufacturer ID, Social Security number, trade and tax identifying numbers, passport number, or account number. Records may also be retrieved by non-personal information such as transaction date, entity or institution name, description of goods, value of transactions, and other information.

SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

ICE is proposing to retain FALCON–DARTTS and FALCON-Roadrunner datasets for ten years. Some of the law enforcement data analyzed by FALCON–DARTTS and FALCON-Roadrunner is already maintained in the FALCON environment and subject to a proposed retention period there; however, FALCON–DARTTS and FALCON-Roadrunner will only access these existing datasets for ten years.

SYSTEM MANAGER AND ADDRESS:

FALCON–DARTTS: Unit Chief, Trade Transparency Unit, ICE Homeland Security Investigations, 500 12th Street SW., Mail Stop 5103, Washington, DC 20536.

FALCON-Roadrunner: Deputy Assistant Director, Counter-Proliferation Investigations Program, ICE Homeland Security Investigations, 500 12th Street SW., Mail Stop 5109, Washington, DC 20536.

NOTIFICATION PROCEDURE:

The Secretary of Homeland Security has exempted this system from notification, access, and amendment because of the law enforcement nature of the information. These exemptions also apply to the extent that information in this system of records is recompiled or is created from information contained in other systems of records. To the extent that a record is exempted in a source system, the exemption will continue to apply. However, ICE will review requests on a case by case to determine if release of the information is appropriate. After conferring with the appropriate component or agency, as applicable, DHS may waive applicable exemptions in appropriate circumstances and when it would not appear to interfere with or adversely affect the law enforcement purposes of the systems from which the information is recompiled or in which it is contained. Additionally, ICE and DHS are not exempting any records that were ingested or indexed by TTAR when the source system of records already provides access and/or amendment under the Privacy Act. Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its

content, may submit a request in writing to the ICE Freedom of Information Act Officer whose contact information can be found at *http://www.dhs.gov/foia* under ''contacts.'' If an individual believes more than one component maintains Privacy Act records concerning him or her the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, Department of Homeland Security, 245 Murray Drive SW., Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity, meaning that you must provide your full name, current address, and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief Freedom of Information Act Officer, *http://www.dhs.gov* or 1–866–431–0486. In addition you should provide the following:

- An explanation of why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created;
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records; and
- If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without this bulleted information the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

Records are obtained from U.S. Customs and Border Protection; U.S. Department of Commerce; U.S. Department of the Treasury; U.S. Department of State; other federal, state, and local law enforcement agencies; foreign governments pursuant to international agreements or arrangements; international entities; financial institutions; transportation companies; manufacturers; customs brokers; free trade zones; port authorities; and commercially and publicly available data sources.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

The Secretary of Homeland Security has exempted portions of this system. Pursuant to exemption 5 U.S.C. 552a(j)(2) of the Privacy Act, portions of this system are exempt from 5 U.S.C. 552a(c)(3) and (4); (d); (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(5) and (e)(8); (f); and (g). Pursuant to 5 U.S.C. 552a(k)(2), this system is exempt from the following provisions of the Privacy Act, subject to the limitations set forth in those subsections: 5 U.S.C. 552a(c)(3); (d); (e)(1), (e)(4)(G), (e)(4)(H); and (f).

Dated: November 12, 2014.

Karen L. Neuman,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2014–28168 Filed 11–28–14; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of NMK Resources, Inc., as a Commercial Laboratory and Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of NMK Resources, Inc., as a commercial laboratory and gauger.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that NMK Resources, Inc. has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of July 10, 2014.

DATES: *Effective Dates:* The accreditation and approval of NMK Resources, Inc., as commercial laboratory and gauger became effective on July 10, 2014. The next triennial inspection date will be scheduled for July 2017.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1331 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, that NMK Resources, Inc., 650 Grove Road, Suite #111, Thorofare, NJ 08086, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. NMK Resources, Inc. is approved for the following gauging procedures for petroleum and certain petroleum products per the American Petroleum Institute (API) Measurement Standards:

API Chapters	Title
3	Tank gauging.
7	Temperature determination.
8	Sampling.
12	Calculations.
17	Maritime measurement.

NMK Resources, Inc. is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–04	ASTM D 95	Standard test method for water in petroleum products and bituminous materials by distillation.
27–11	ASTM D 445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (the Calculation of Dynamic Velocity).
27–13	ASTM D 4294	Standard test method for sulfur in petroleum and petroleum products by energy-dispersive x-ray fluorescence spectrometry.

CBPL No.	ASTM	Title
27–48	ASTM D 4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.

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, inquiries 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://www.cbp.gov/sites/default/files/documents/gaulist_3.pdf*.

Dated: November 20, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2014–28292 Filed 11–28–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of NMK Resources, Inc., as a Commercial Laboratory and Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of NMK Resources, Inc., as a commercial laboratory and gauger.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that NMK Resources, Inc. has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of June 6, 2014.

DATES: *Effective Dates:* The accreditation and approval of NMK Resources, Inc., as commercial laboratory and gauger became effective on June 6, 2014. The next triennial inspection date will be scheduled for June 2017.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1331 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, that NMK Resources, Inc., 1100 Walnut St., Roselle, NJ 07203, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. NMK Resources, Inc. is approved for the following gauging procedures for petroleum and certain petroleum products per the American Petroleum Institute (API) Measurement Standards:

API Chapters	Title
3	Tank gauging.
7	Temperature determination.
8	Sampling.
12	Calculations.
17	Maritime measurement.

NMK Resources, Inc. is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–04	ASTM D 95	Standard test method for water in petroleum products and bituminous materials by distillation.
27–06	ASTM D 473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–11	ASTM D 445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (the Calculation of Dynamic Velocity).
27–13	ASTM D 4294	Standard test method for sulfur in petroleum and petroleum products by energy-dispersive x-ray fluorescence spectrometry.
27–48	ASTM D 4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.

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, inquiries 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://www.cbp.gov/sites/default/files/documents/gaulist_3.pdf*.

Dated: November 11, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2014–28294 Filed 11–28–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Thionville Surveying Company, 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 Thionville Surveying Company, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Thionville Surveying Company, Inc. has been approved to gauge animal and vegetable oils and accredited to test certain animal and vegetable oils for customs purposes for the next three years as of May 14, 2014.

DATES: *Effective Dates:* The accreditation and approval of Thionville Surveying Company, Inc., as commercial gauger and laboratory became effective on May 14, 2014. The next triennial inspection date will be scheduled for May 2017.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1331 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, that Thionville Surveying Company, Inc., 5440 Pepsi Street, Harahan, LA 70123, has been approved to gauge animal and vegetable oils and accredited to test certain animal and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Thionville Surveying Company, Inc. is approved for the following gauging procedures for animal and vegetable oils per the National Institute of Oilseed Products (NIOP) standards:

CBPL No.	Method	Title
n/a	NIOP 5.10.5	Weight Determination/Gauging.

Thionville Surveying Company, Inc. is accredited for the following laboratory analysis procedures and methods for certain animal and vegetable oils set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL), the International Standards Organization (ISO), and the American Oil Chemists' Society (AOCS):

CBPL No.	ASTM	Title
15–02	AOCS Ca 5a–40	Free Fatty Acids.
n/a	AOCS Ce 2–66	Preparation of Methyl Esters of Fatty Acids.
n/a	AOCS Ce 1a–13	Determination of Fatty Acids in Edible Oils and Fats by Capillary GLC.
n/a	AOCS Ce 1h–05	Determination of *cis-, trans-,* Saturated, Monounsaturated and Polyunsaturated Fatty Acids in Vegetable or Non-Ruminant Animal Oils and Fats by Capillary GLC.
n/a	ISO 18301	Animal and Vegetable fats and oils—Determination of conventional mass per volume (litre weight in air)—Oscillating U-tube method.

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, inquiries 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://www.cbp.gov/sites/default/files/documents/gaulist_3.pdf*.

Dated: November 18, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2014–28295 Filed 11–28–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–17082; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Carnegie Museum of Natural History, Pittsburgh, PA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Carnegie Museum of Natural History has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Carnegie Museum of Natural History. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Carnegie Museum of Natural History at the address in this notice by December 31, 2014.

ADDRESSES: Deborah G. Harding, Carnegie Museum of Natural History, 5800 Baum Blvd., Pittsburgh, PA 15206, telephone (412) 665–2606.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the

Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Carnegie Museum of Natural History, Pittsburgh, PA. The human remains and associated funerary objects were removed with the Chambers Site, 36LR11, Lawrence County, PA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Carnegie Museum of Natural History professional staff in consultation with representatives of the Delaware Tribe of Indians.

History and Description of the Remains

Between 1957 and 1959, human remains representing, at minimum, 67 individuals were removed from the Chambers Site (36 LR 11), Union Township, Lawrence County, PA, by John A. Zakucia. In 1959, Zakucia donated 55 individuals and associated funerary objects to the Carnegie Museum of Natural History (CMNH). In 1959, CMNH conducted limited excavations at the Chambers site by then-Curator, Don W. Dragoo, and removed 12 additional individuals. No known individuals were identified. The 2,564 associated funerary objects include 2,255 glass seed; 8 tubular beads; 1 mass of seed beads in matrix (uncounted); 9 copper alloy tinklers; 140 wrought iron nails and fragments and attached wood (coffin fragments); 2 hawk bells; 2 thimbles; 1 copper alloy brooch or buckle; 1 braided wire bracelet; 1 silver band or bracelet; 1 copper alloy bracelet; 1 iron knife blade; 15 grit-tempered pottery fragments; 32 fragments of non-human bone (deer, sheep or goat, pig, and cow); 20 chipped stone tools; 52 chipped stone flakes and fragments; 3 ground stone pieces; 5 projectile points; 4 hammerstones; 2 hematite fragments; 5 pieces of charcoal; 1 piece of bark or fabric; 1 tiny fragment of organic material; 1 lump of matrix containing bone or metal fragments; and 1 natural stone.

The Euromerican assemblage of objects associated with the human remains dates the burials to the 18th century. Ethnohistoric and documentary evidence identify the Chambers site as a Lenape (Delaware) occupation dating to A.C.E. 1763–1776. There is no evidence to contradict this.

Determinations Made by the Carnegie Museum of Natural History

Officials of the Carnegie Museum of Natural History have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 55 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 2,564 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects to the Delaware Tribe of Indians.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Deborah G. Harding, Carnegie Museum of Natural History, 5800 Baum Blvd., Pittsburgh, PA 15206, telephone (412) 665–2606, by December 31, 2014. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Delaware Tribe of Indians may proceed.

The Carnegie Museum of Natural History is responsible for notifying the Delaware Tribe of Indians that this notice has been published.

Dated: October 30, 2014.

Melanie O'Brien,

Acting Manager, National NAGPRA Program.

[FR Doc. 2014–28279 Filed 11–28–14; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–16305; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of Defense, Army, Fort Sill National Historic Landmark and Museum, Fort Sill, OK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Fort Sill National Historic Landmark and Museum has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, and has determined that a relationship of lineal descent has been established between the human remains and associated funerary objects of an identified individual and the individual's descendants. Lineal descendants not identified in this notice who wish to request transfer of control of these human remains and associated funerary objects should submit a written request to Fort Sill National Historic Landmark and Museum. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants stated in this notice may proceed.

DATES: Lineal descendants not identified in this notice who wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Fort Sill National Historic Landmark and Museum at the address in this notice by December 31, 2014.

ADDRESSES: Dr. Scott A. Neel, Director, Fort Sill National Historic Landmark and Museum, U.S. Army Fires Center of Excellence, Fort Sill, OK 73503, telephone (580) 442–6570, email *scott.a.neel2.civ@mail.mil*.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Fort Sill National Historic Landmark and Museum, Fort Sill, OK. The human remains and associated funerary objects were removed from a gravesite of an identified individual near Anadarko, OK.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25

U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Fort Sill National Historic Landmark and Museum and Fort Sill Environmental Quality Division professional staff in consultation with representatives of the Apache Tribe of Oklahoma; Caddo Nation of Oklahoma; Cheyenne and Arapaho Tribes, Oklahoma (previously listed as Cheyenne-Arapaho Tribes of Oklahoma); Comanche Nation, Oklahoma; Delaware Nation, Oklahoma; Fort Sill Apache Tribe of Oklahoma; Kiowa Indian Tribe of Oklahoma; The Chickasaw Nation; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma. The Delaware Nation, Oklahoma, Tribal Historic Preservation Officer and her staff, and other administrative staff, met with members of the Fort Sill National Historic Landmark and Museum and Fort Sill Environmental Quality Division staff on November 14, 2013, and examined the human remains and associated funerary objects.

History and Description of the Remains

In 1975, human remains representing, at minimum, one individual were removed from the original gravesite of Black Beaver near his home in Anadarko, Caddo County, OK. The human remains were exhumed for reburial in Chief's Knoll at the Fort Sill Post Cemetery. The human remains and associated funerary objects were not reinterred at Chief's Knoll. Black Beaver was a Delaware Chief. He was born in 1806 and died in 1886. The 52 associated funerary objects are 11 burnt clay and rocks, 12 animal bones, 2 glass fragments, 14 metal buttons or rivets, 3 plastic buttons, 4 unidentified pieces of metal, 2 lots of scraps of fabric, 1 lot of soil, 1 lot of wood fragments, and 2 lots of wood and nails from the coffin.

Kerry Holton has submitted a request for the human remains and associated funerary objects listed in this notice on behalf of himself and other relatives who are known lineal descendants of Black Beaver. Holton provided genealogical evidence tracing his direct lineal descent from Black Beaver. Harold Pruner and Kelli Line have also submitted genealogical evidence on behalf of themselves and additional named and unnamed descendants.

Determinations Made by the Fort Sill National Historic Landmark and Museum

Officials of the Fort Sill National Historic Landmark and Museum have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 52 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 43 CFR 10.14(b), there is a relationship of lineal descent that can be traced between the human remains and associated funerary objects of an identified individual, Black Beaver, and Kerry Holton, Harold Pruner, Kelli Line, and additional named and unnamed descendants who have come forward.

Additional Requestors and Disposition

Lineal descendants not identified in this notice who wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Dr. Scott A. Neel, Director, Fort Sill National Historic Landmark and Museum, U.S. Army Fires Center of Excellence, Fort Sill, OK 73503, telephone (580) 442–6570, email *scott.a.neel2.civ@mail.mil*, by December 31, 2014. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects of Black Beaver to Kerry Holton, Harold Pruner, and Kelli Line on behalf of themselves and other known lineal descendants may proceed.

The Fort Sill National Historic Landmark and Museum is responsible for notifying the Apache Tribe of Oklahoma; Caddo Nation of Oklahoma; Cheyenne and Arapaho Tribes, Oklahoma (previously listed as Cheyenne-Arapaho Tribes of Oklahoma); Comanche Nation, Oklahoma; Delaware Nation, Oklahoma; Fort Sill Apache Tribe of Oklahoma; Kiowa Indian Tribe of Oklahoma; The Chickasaw Nation; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma, that this notice has been published.

Dated: November 14, 2014.

Melanie O'Brien,

Acting Manager, National NAGPRA Program.

[FR Doc. 2014–28280 Filed 11–28–14; 8:45 am]

BILLING CODE 4312–50–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–463 and 731–TA–1159 (Review)]

Oil Country Tubular Goods From China; Institution of Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)) (the Act) to determine whether revocation of the antidumping and countervailing duty orders on oil country tubular goods (''OCTG'') from China would be likely to lead to continuation or recurrence of material injury. Pursuant to section 751(c)(2) of the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; [1] to be assured of consideration, the deadline for responses is December 31, 2014. Comments on the adequacy of responses may be filed with the Commission by February 12, 2015. For further information concerning the conduct of this proceeding 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).

DATES: *Effective Date:* December 1, 2014.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), 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 this proceeding may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

[1] No response to this request for information is required if a currently valid Office of Management and Budget (OMB) number is not displayed; the OMB number is 3117–0016/USITC No. 14–5–323, expiration date June 30, 2017. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436.

SUPPLEMENTARY INFORMATION:

Background.—On January 20, 2010, the Department of Commerce issued a countervailing duty order on imports of OCTG from China (75 FR 3203). On May 21, 2010, the Department of Commerce issued an antidumping duty order on imports of OCTG from China (75 FR 28551). The Commission is conducting reviews to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. It will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct full or expedited reviews. The Commission's determinations in any expedited reviews will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to these reviews:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year reviews, as defined by the Department of Commerce.

(2) The *Subject Country* in these reviews is China.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determinations, the Commission defined a single domestic like product, consisting of all OCTG, that is co-extensive with Commerce's scope.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determinations, the Commission defined a single *Domestic Industry* consisting of all domestic producers of OCTG.

(5) The *Order Date* is the date that the antidumping and countervailing duty orders under review became effective. In the review concerning the countervailing duty order, the *Order Date* is January 20, 2010. In the review concerning the antidumping duty order, the *Order Date* is May 21, 2010.

(6) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding 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 proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Carol McCue Verratti, Deputy Agency Ethics Official, at 202–205–3088.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

Written submissions.—Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is December 31, 2014. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is February 12, 2015. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to filing have changed. The most recent amendments took effect on July 25, 2014. *See* 79 FR 35920 (June 25, 2014), and the revised Commission Handbook on E-filing, available from the Commission's Web site at *http://edis.usitc.gov.* Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Inability to provide requested information.—Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide

equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determinations in the reviews.

Information To Be Provided In Response To This Notice Of Institution: As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise,* a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping and countervailing duty orders on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries since the *Order Dates.*

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2013, except as noted (report quantity data in short tons and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2013 (report quantity data in short tons and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2013 (report quantity data in short tons and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* since the *Order Dates,* and significant changes, if any,

that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: November 19, 2014.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2014–27734 Filed 11–28–14; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Wireless Devices, Including Mobile Phones and Tablets III, DN 3043;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *EDIS*,[1] and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission (USITC) at *USITC*.[2] The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *EDIS*.[3] Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Pragmatus Mobile, LLC on November 24, 2014. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain wireless devices, including mobile phones and tablets III. The complaint names as respondents ASUSTeK Computer, Inc. of Taiwan; ASUS Computer International, Inc. of Fremont, CA; and ASUS Technology Pte. Ltd. of Singapore. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3043'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures[4]). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such

[1] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

[2] United States International Trade Commission (USITC): *http://edis.usitc.gov.*

[3] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

[4] Handbook for Electronic Filing Procedures: *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf.*

treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[5]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: November 24, 2014.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2014–28170 Filed 11–28–14; 8:45 am]

BILLING CODE 7020–02–P

JOINT BOARD FOR THE ENROLLMENT OF ACTUARIES

Meeting of the Advisory Committee

AGENCY: Joint Board for the Enrollment of Actuaries.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Executive Director of the Joint Board for the Enrollment of Actuaries gives notice of a meeting of the Advisory Committee on Actuarial Examinations (portions of which will be open to the public) in Washington, DC, on January 8–9, 2015.

DATES: Thursday, January 8, 2015, from 9:00 a.m. to 5:00 p.m., and Friday, January 9, 2015, from 8:30 a.m. to 5:00 p.m.

ADDRESSES: The meeting will be held at the Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Patrick W. McDonough, Executive Director of the Joint Board for the Enrollment of Actuaries, 703–414–2173.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Advisory Committee on Actuarial Examinations will meet at the Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, on Thursday, January 8, 2015, from 9:00 a.m. to 5:00 p.m., and Friday, January 9, 2015, from 8:30 a.m. to 5:00 p.m.

The purpose of the meeting is to discuss topics and questions that may be recommended for inclusion on future Joint Board examinations in actuarial mathematics and methodology referred to in 29 U.S.C. 1242(a)(1)(B) and to review the November 2014 Pension (EA–2F) Examination in order to make recommendations relative thereto, including the minimum acceptable pass score. Topics for inclusion on the syllabus for the Joint Board's examination program for the May 2015 Basic (EA–1) Examination and the May 2015 Pension (EA–2L) Examination will be discussed.

A determination has been made as required by section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. App., that the portions of the meeting dealing with the discussion of questions that may appear on the Joint Board's examinations and the review of the November 2014 Pension (EA–2F) Examination fall within the exceptions to the open meeting requirement set forth in 5 U.S.C. 552b(c)(9)(B), and that the public interest requires that such portions be closed to public participation.

The portion of the meeting dealing with the discussion of the other topics will commence at 1:00 p.m. on January 9, 2015, and will continue for as long as necessary to complete the discussion, but not beyond 3:00 p.m. Time permitting, after the close of this discussion by Committee members, interested persons may make statements germane to this subject. Persons wishing to make oral statements should notify the Executive Director in writing prior to the meeting in order to aid in scheduling the time available and should submit the written text, or at a minimum, an outline of comments they propose to make orally. Such comments will be limited to 10 minutes in length. All persons planning to attend the public session should notify the Executive Director in writing to obtain building entry. Notifications of intent to make an oral statement or to attend must be sent electronically, by no later than December 30, 2014, to *Patrick.Mcdonough@irs.gov*. Any interested person also may file a written statement for consideration by the Joint Board and the Committee by sending it to: Internal Revenue Service; Attn: Patrick W. McDonough, Executive Director; Joint Board for the Enrollment of Actuaries SE:RPO; REFM, Park 4, Floor 4; 1111 Constitution Avenue NW., Washington, DC 20224.

Dated: November 24, 2014.

Patrick W. McDonough,

Executive Director, Joint Board for the Enrollment of Actuaries.

[FR Doc. 2014–28156 Filed 11–28–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0008]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Application and Permit for Permanent Exportation of Firearms

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit 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.

DATES: Comments are encouraged and will be accepted for 60 days until January 30, 2015.

FOR FURTHER INFORMATION CONTACT: 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 Gary Schaible, National Firearms Act Branch at *nfaombcomments@atf.gov* .

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the 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.

[5] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

Overview of this information collection 1140–0008:

1. *Type of Information Collection:* Extension without change of an existing collection.

2. *The Title of the Form/Collection:* Application and Permit for Permanent Exportation of Firearms.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 9 (5320.9).

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: Individual or households.

Abstract: The form is used to obtain permission to export firearms and serves as a vehicle to allow either the removal of the firearm from registration in the National Firearms Registration and Transfer Record or collection of an excise tax. It is used by Federal firearms licensees and others to obtain a benefit.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 930 respondents will take 18 minutes to complete the form.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 279 hours.

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., Room 3E.405B, Washington, DC 20530.

Dated: November 25, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014–28205 Filed 11–28–14; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0052]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Information Collection; Claims Filed Under the Radiation Exposure Compensation Act (RECA)

AGENCY: Civil Division, Department of Justice.

ACTION: 30-day notice.

SUMMARY: The Department of Justice (DOJ), Civil Division, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 79, Number 187, page 57977, on September 26, 2014, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for an additional days until December 31, 2014.

FOR FURTHER INFORMATION CONTACT: 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 the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: DOJ Desk Officer. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20530 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the 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/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:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Claims Filed Under the Radiation Exposure Compensation Act (RECA).

3. *The agency form number:* Form Number: N/A.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals or households.

Abstract: Information is collected to determine whether an individual is entitled to compensation under the Radiation Exposure Compensation Act.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 2,000 respondents will complete the form annually within approximately 2.5 hours.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 5,000 total annual 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., 3E.405B, Washington, DC 20530.

Dated: November 25, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014–28208 Filed 11–28–14; 8:45 am]

BILLING CODE 4410–12–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0197]

Agency Information Collection Activities; Proposed Collection Comments Requested; Bureau of Justice Assistance Application Form: State Criminal Alien Assistance Program (SCAAP)

AGENCY: Bureau of Justice Assistance, Department of Justice.

ACTION: 30-day notice.

SUMMARY: The Department of Justice, Office of Justice Programs, Bureau of Justice Assistance, will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for an additional 30 days until December 31, 2014.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact C. Casto at 1–202–353–7193, Bureau of Justice Assistance, Office of Justice Programs, U.S. Department of Justice, 810 7th Street NW., Washington, DC 20531 or by email at *Chris.Casto@usdoj.gov*.

Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20530 or sent to *OIRA_submissions@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: 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:* Extension of currently approved collection.

2. *The Title of the Form/Collection: State Criminal Alien Assistance Program*

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* None. Bureau of Justice Assistance, Office of Justice Programs, United States Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Eligible state, local, or tribal agency that has authority over correctional facilities and incurred costs related to detaining certain categories of undocumented criminal aliens and the costs associated with the housing said aliens covered by the SCAAP law.

Abstract: In response to the Violent Crime Control and Law Enforcement Act of 1994 Section 130002(b) as amended in 1996, the Office of Justice Programs' (OJP) Bureau of Justice Assistance (BJA) administers the State Criminal Alien Assistance Program (SCAAP) with the U.S. Immigration and Customs Enforcement (ICE), a component of the Department of Homeland Security (DHS). SCAAP provides federal payments to states and localities that incurred correctional officer salary costs for incarcerating undocumented criminal aliens with at least one felony or two misdemeanor convictions for violations of state or local law, and who are incarcerated for at least 4 consecutive days during the designated reporting period. SCAAP is governed by Section 242 of the Immigration and Nationality Act, 8 U.S.C. 1231(i), as amended, and Title II, Subtitle C, Section 20301, Violent Crime Control and Law Enforcement Act of 1994, Public Law 103–322.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that no more than 887 respondents will apply each year. Each application takes approximately 90 minutes to complete.

6. *An estimate of the total public burden (in hours) associated with the collection:* An estimate of the total public burden (in hours) associated with the collection is 1,330.50 hours. Total Annual Reporting Burden: 887×1.5 hours per application = 1,330.50.

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., 3E.405B, Washington, DC 20530.

Dated: November 25, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014–28207 Filed 11–28–14; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0010]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Application To Transport Interstate or Temporarily Export Certain National Firearms Act (NFA) Firearms

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit 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.

DATES: Comments are encouraged and will be accepted for 60 days until January 30, 2015.

FOR FURTHER INFORMATION CONTACT: 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 Andrew Ashton, National Firearms Act Branch at *nfaombcomments@atf.gov* .

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the 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 1140–0010:

1. *Type of Information Collection:* Extension without change of an existing collection.

2. *The Title of the Form/Collection:* Application to Transport Interstate or Temporarily Export Certain National Firearms Act (NFA) Firearms.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 5320.20.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individual or households.

Other: None.

Abstract: The information is used by ATF to determine the lawful transportation of an NFA firearm and/or to pursue the criminal investigation into an unregistered NFA firearm.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 7200 respondents will take 20 minutes to complete the form.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 2400 hours.

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., Room 3E–405B, Washington, DC 20530.

Dated: November 25, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014–28206 Filed 11–28–14; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Modification Under the Clean Water Act

On November 21, 2014, the Department of Justice lodged a proposed Agreed Consent Decree Modification with the United States District Court for the Northern District of Indiana in the lawsuit entitled *United States and State of Indiana* v. *The City of Fort Wayne, Indiana,* Civil Action No. 2:07–cv–00445–PPS–APR.

The United States and State of Indiana (State) previously filed a complaint against Fort Wayne for violations of the Clean Water Act, 33 U.S.C. §1251 *et seq.,* in connection with the City of Fort Wayne's operation of its municipal wastewater and sewer system. On April 1, 2008, the Court entered a Consent Decree between the parties that required Fort Wayne to implement various injunctive measures to address its combined sewer overflows (CSOs) and sanitary sewer overflows (SSOs). Under the Consent Decree, the injunctive relief is to be implemented over an 18-year period and is designed to eliminate SSOs and reduce the number of CSOs to approximately one per year on the St. Joseph River and four per year on the St. Marys and Maumee Rivers.

In the process of implementing the injunctive relief, Fort Wayne developed, and proposed to the regulators, an alternative remedy for CSOs 45, 51, 53, 68, and 52, which discharge to the St. Joseph River. The alternative approach will achieve the same level of control as required by the Decree, but will cost less and be completed considerably sooner—by December 2015 instead of December 2019. In addition, Fort Wayne is in the process of developing an alternative approach for CSO Control Measure 9 to address CSOs 54, 61, and 62, which discharge to the St. Marys and Maumee Rivers. The parties have agreed to revise the Consent Decree to allow Fort Wayne to propose a revised solution, subject to the regulators' approval in accordance with a process set forth in the Decree, as long as any such proposal is submitted by December 15, 2016 and meets the Performance Criteria and Critical Milestones previously agreed to for Control Measure 9. Finally, the parties have agreed to correct a typographical error concerning CSO Control Measure 9. This Control Measure must be designed to achieve a Performance Criterion of 4 CSO events in a typical year as correctly set forth in Appendix 3, footnote 7, and not one overflow per year, as incorrectly set forth in the text box of Appendix 3 that describes CSO Control Measure 9. The proposed Agreed Consent Decree Modification incorporates all of these changes.

The publication of this notice opens a period for public comment on the proposed Agreed Consent Decree Modification. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and State of Indiana* v. *The City of Fort Wayne, Indiana,* D.J. Ref. No. 90–5–1–1–07653. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Agreed Consent Decree Modification may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Agreed Consent Decree Modification upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $8.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Randall M. Stone,

Acting Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2014–28203 Filed 11–28–14; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Office of the Secretary

Notice of Publication of 2014 Update to the Department of Labor's List of Goods Produced by Child Labor or Forced Labor

AGENCY: Bureau of International Labor Affairs, Department of Labor.

ACTION: Announcement of public availability of updated list of goods.

SUMMARY: This notice announces the publication of an updated list of goods—along with countries of origin—that the Bureau of International Labor Affairs (ILAB) has reason to believe are produced by child labor or forced labor in violation of international standards (the List). ILAB is required to develop and make available to the public the List pursuant to the Trafficking Victims Protection Reauthorization Act (TVPRA) of 2005, as amended.

FOR FURTHER INFORMATION CONTACT: Director, Office of Child Labor, Forced Labor, and Human Trafficking, Bureau

of International Labor Affairs, U.S. Department of Labor, at (202) 693–4843 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: ILAB announces the publication of the sixth edition of the *List of Goods Produced by Child Labor or Forced Labor,* pursuant to the TVPRA of 2005, as amended. ILAB published the initial List on September 10, 2009, and has since published updated editions annually. Beginning this year, ILAB will update and publish the List every other year, pursuant to changes in the law enacted in 2013. See 22 U.S.C. 7112(b). The 2014 edition adds two new goods (alcoholic beverages and meat), and one new country (Yemen) to the List.

Section 105(b) of the TVPRA mandates that ILAB develop and publish a list of goods from countries that ILAB ''has reason to believe are produced with child labor or forced labor in violation of international standards.'' 22 U.S.C. 7112(b)(2). ILAB's Office of Child Labor, Forced Labor, and Human Trafficking carries out this mandate. The primary purposes of the List are to raise public awareness about the incidence of child labor and forced labor in the production of goods in the countries listed and to promote efforts to eliminate such practices. A full report, including the updated List and a discussion of the List's methodology, as well as Frequently Asked Questions and a bibliography of sources, are available on the Department of Labor Web site at: *http://www.dol.gov/ilab/reports/child-labor/list-of-goods/*.

Signed at Washington, DC, this 14th day of November 2014.

Carol Pier,

Deputy Undersecretary for International Affairs.

[FR Doc. 2014–27623 Filed 11–28–14; 8:45 am]

BILLING CODE 4510–28–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0004]

Proposed Information Collection; Roof Control Plans for Underground Coal Mines

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A). This program helps to assure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection for Roof Control Plans for Underground Coal Mines.

DATES: All comments must be received on or before January 30, 2015.

ADDRESSES: Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below.

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments for docket number MSHA–2014–0010
- *Regular Mail:* Send comments to MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, VA 22209–3939.
- *Hand Delivery:* MSHA, 1100 Wilson Boulevard, Room 2350, Arlington, VA. Sign in at the receptionist's desk on the 21st floor.

FOR FURTHER INFORMATION CONTACT: Sheila McConnell, Acting Director, Office of Standards, Regulations, and Variances, MSHA, at *MSHA.information.collections@dol.gov* (email); 202–693–9440 (voice); or 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 813(h), authorizes MSHA to collect information necessary to carry out its duty in protecting the safety and health of miners. Further, Section 101(a) of the Mine Act, 30 U.S.C. 811 authorizes the Secretary to develop, promulgate, and revise as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal or other mines.

Section 302(a) of the Federal Mine Safety and Health Act of 1977 (Mine Act) 30 U.S.C. 846, requires that a roof control plan and revisions thereof suitable to the roof conditions and mining system of each coal mine be first approved by the Secretary of Labor (Secretary) before implementation by the operator. The plan must show the type of support and spacing approved by the Secretary, and the plan must be reviewed at least every six months by the Secretary.

This information collection addresses the recordkeeping associated with:

75.220(a)(1)—Roof control plan
75.221(1)(2)—Roof control plan information
75.222(a)—Roof control plan-approval
75.223(a), (b), & (d)—Evaluation and revision of roof control plan

II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection related to Roof Control Plans for Underground Coal Mines. MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;
- Evaluate the accuracy of the MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to 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.

This information collection request is available on *http://www.msha.gov/regs/fedreg/informationcollection/informationcollection.asp.* The information collection request will be available on MSHA's Web site and on *http://www.regulations.gov.* MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on *www.regulations.gov* and *www.reginfo.gov.*

The public may also examine publicly available documents at MSHA, 1100 Wilson Boulevard, Room 2350, Arlington, VA. Sign in at the receptionist's desk on the 21st floor.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION** section of this notice.

III. Current Actions

This request for collection of information contains provisions for Roof Control Plans for Underground Coal

Mines. MSHA has updated the data in respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection extension request.

Type of Review: Extension, without change, of a currently approved collection.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0004.

Affected Public: Business or other for-profit.

Number of Respondents: 494.

Frequency: Annually.

Number of Responses: 1,965.

Annual Burden Hours: 7,924 hours.

Annual Respondent or Recordkeeper Cost: $6,795.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: November 25, 2014.

Sheila McConnell,

Certifying Officer.

[FR Doc. 2014–28171 Filed 11–28–14; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Proposed Renewal of Existing Collection; Comment Request

AGENCY: Division of Longshore and Harbor Workers' Compensation, Office of Workers' Compensation Programs, Labor.

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)] This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Workers' Compensation (OWCP) is soliciting comments concerning the proposed collection: Notice of Controversion of Right to Compensation (LS–207). A copy of the proposed information collection request can be obtained by contacting the office listed below in the address section of this Notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before January 30, 2015.

ADDRESSES: Ms. Yoon Ferguson, U.S. Department of Labor, 200 Constitution Ave. NW., Room S–3323, Washington, DC 20210, telephone (202) 693–0701, fax (202) 693–1449, Email *ferguson.yoon@dol.gov.* Please use only one method of transmission for comments (mail, fax, or Email).

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Workers' Compensation Programs (OWCP) administers the Longshore and Harbor Workers' Compensation Act (LHWCA). The Act provides benefits to workers' injured in maritime employment on the navigable waters of the United States or in an adjoining area customarily used by an employer in loading, unloading, repairing, or building a vessel. In addition, several acts extend the Longshore Act's coverage to certain other employees. Pursuant to section 914(d) of the Longshore Act, and 20CFR702.251, if an employer controverts the right to compensation, he/she shall file with the district director in the affected compensation district on or before the fourteenth day after he/she has knowledge of the alleged injury or death, a notice, in accordance with a form prescribed by the Secretary, stating that the right to compensation is controverted. Form LS–207 has been designated for this purpose. Form LS–207 is used by insurance carriers and self-insured employers to controvert claims under the Longshore Act and extensions. The information is used by OWCP district offices to determine the basis for not paying benefits in a case. This information collection is currently approved for use through February 28, 2015.

II. Review Focus

The Department of Labor is particularly interested in comments which:

* Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

* evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

* enhance the quality, utility and clarity of the information to be collected; and

* minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. Current Actions

The Department of Labor seeks the extension of approval of this information collection in order to carry out its responsibility to meet the statutory requirements to provide compensation or death benefits under the Act to workers covered by the Act.

Agency: Office of Workers' Compensation Programs.

Type of Review: Extension.

Title: Notice of Controversion of Right to Compensation.

OMB Number: 1240–0042.

Agency Number: LS–207.

Affected Public: Business or other for-profit.

Total Respondents: 600.

Total Annual Responses: 18,000.

Estimated Total Burden Hours: 4,500.

Estimated Time per Response: 15 minutes.

Frequency: On occasion.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $9,360.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: November 25, 2014.

Yoon Ferguson,

Agency Clearance Officer, Office of Workers' Compensation Programs, U.S. Department of Labor.

[FR Doc. 2014–28199 Filed 11–28–14; 8:45 am]

BILLING CODE 4510–CF–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Proposed Renewal of Existing Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce

paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)] This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Workers' Compensation Programs (OWCP) is soliciting comments concerning the proposed collection: Notice of Final Payment or Suspension of Compensation Benefits (LS–208). A copy of the proposed information collection request can be obtained by contacting the office listed below in the address section of this Notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before January 30, 2015.

ADDRESSES: Ms. Yoon Ferguson, U.S. Department of Labor, 200 Constitution Ave. NW., Room S–3323, Washington, DC 20210, telephone (202) 693–0701, fax (202) 693–1449, Email *ferguson.yoon@dol.gov.* Please use only one method of transmission for comments (mail, fax, or Email).

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Workers' Compensation Programs (OWCP) administers the Longshore and Harbor Workers' Compensation Act (LHWCA). The Act provides benefits to workers' injured in maritime employment on the navigable waters of the United States or in an adjoining area customarily used by an employer in loading, unloading, repairing, or building a vessel. In addition, several acts extend the Longshore Act's coverage to certain other employees.

Under Section 914(g) of the Longshore Act, the employer or its insurance carrier must file a report of the compensation paid to a claimant at the time final payment is made. The Act requires that the form must be filed within sixteen days of the final payment of compensation with the District Director in the compensation district in which the injury occurred. The form requests information regarding the beginning and ending dates of compensation payments, compensation rates, reason payments were terminated and types and amount of compensation payments. Filing of the report is mandatory, and failure to do so is subject to a civil penalty. This information collection is currently approved for use through February 28, 2015.

II. Review Focus

The Department of Labor is particularly interested in comments which:

* Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

* evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

* enhance the quality, utility and clarity of the information to be collected; and

* minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. Current Actions

The Department of Labor seeks the extension of approval of this information collection in order to carry out its responsibility to meet the statutory requirements to provide compensation or death benefits under the Act to workers covered by the Act.

Agency: Office of Workers' Compensation Programs.

Type of Review: Extension.

Title: Notice of Final Payment or Suspension of Compensation Benefits.

OMB Number: 1240–0041.

Agency Number: LS–208.

Affected Public: Business or other for-profit.

Total Respondents: 600.

Total Annual Responses: 21,000.

Estimated Total Burden Hours: 5,250.

Estimated Time per Response: 15 minutes.

Frequency: On occasion.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $10,920.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: November 25, 2014.

Yoon Ferguson,

Agency Clearance Officer, Office of Workers' Compensation Programs, U.S. Department of Labor.

[FR Doc. 2014–28201 Filed 11–28–14; 8:45 am]

BILLING CODE 4510–CF–P

OFFICE OF NATIONAL DRUG CONTROL POLICY

Paperwork Reduction Act; Proposed Collection; Comment Request

AGENCY: Office of National Drug Control Policy.

ACTION: 60-Day notice and request for comments. Revision of Currently Approved Collection: Drug-Free Communities Support Program National Evaluation.

SUMMARY: The Office of National Drug Control Policy (ONDCP) intends to submit the following information collection request to the Office of Management and Budget for review and approval under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: ONDCP encourages and will accept public comments on or before 60 days after the date of this publication.

ADDRESS: Address all comments in writing within 60 days to Helen Hernandez. Facsimile and email are the most reliable means of communication. Ms. Hernandez's facsimile number is (202) 395–6641, and her email address is *Hhernandez@ondcp.eop.gov.* Mailing address is: Executive Office of the President, Office of National Drug Control Policy, Drug-Free Communities (DFC) Support Program, 750 17th Street NW., Washington, DC 20503. For further information, contact Ms. Hernandez at 202–395–6665.

Abstract: ONDCP administers the Drug-Free Communities (DFC) Support Program in partnership with the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP). The DFC Program has two primary goals: To reduce youth substance abuse, and to support community anti-drug coalitions by establishing, strengthening, and fostering collaboration among public and private agencies.

Under reauthorization legislation (21 U.S.C. 1702), Congress mandated evaluation of the DFC Program to determine its effectiveness in meeting objectives. In 2009, a contract was awarded to evaluate the DFC Program which used an existing web-based performance system, called the

Coalition Online Management and Evaluation Tool (COMET) and the Coalition Classification Tool (CCT), to gather information from DFC grantees. The COMET data collection system will be used for FY 2014 DFC grantees and SAMHSA CSAP's Sober Truth on Preventing Underage Drinking Reauthorization Act (''STOP Act'') grantees. (STOP Act data collection is authorized and required by 42 U.S.C. 290bb–35b and Section 519B of the Public Health Service Act).

ONDCP will be awarding a contract for a DFC grant oversight system at the end of 2014, following a competitive request for proposals process. Currently, DFC grantees interact with multiple separate systems. ONDCP plans to have a newly improved grant oversight system with a data collection platform, which will replace the current COMET system. The development and implementation of the DFC grant system will strengthen ONDCP's continued oversight of the DFC program. The data collected will have minimal substantive changes compared to what is currently collected and the system for data collection is intended to be more user friendly to reduce the burden on grantees. For FY 2015 and 2016 grantees, ONDCP/DFC expects a similar data collection system to be fully functional for DFC data collection and STOP Act data collection.

ONDCP's Drug Free Communities office will continue to utilize the case study protocols previously approved by OMB to document coalition practices, successes and challenges. Approximately nine DFC grantees are selected each year to highlight in the case studies. The information from the case studies will be used to illustrate not only what works to reduce drug use in a community setting, but also how and why it works.

Type of Information Collection: Web-based data collection, surveys and interviews of DFC and Sober Truth on Preventing Underage Drinking (STOP) Act grantees.

Title: Drug-Free Communities (DFC) Support Program National Evaluation.

Frequency: Semi-annually by DFC and STOP Act Program Directors via COMET, and annually for DFC Program Directors and selected coalition members via the CCT. Case study interviews and electronic surveys of Program Directors and electronic surveys of selected coalition members will be accomplished one time. ONDCP plans to award a contract for the new data collection system at the end of 2014. For FY 2015 and 2016 grantees, ONDCP/DFC expects a similar data collection system to be fully functional for DFC data collection and STOP Act data collection.

Affected Public: DFC and STOP Act grantees.

Estimated Burden: ONDCP expects that the time required to complete each semi-annual report via COMET will be approximately five hours, and each CCT report will take approximately one hour to complete. Face to face interviews will take 1.5–2 hours and surveys will take approximately .25 hours each to complete. The estimated total amount of time required by all respondents over one year, including Program Directors and grantees to complete COMET, CCT, surveys, and interviews, is 9,680 hours. ONDCP estimates that DFC grantees will spend approximately the same amount or less when using the new DFC data collection system.

Goals: ONDCP intends to use the data of the DFC National Evaluation to assess the DFC Program's effectiveness in preventing and reducing youth substance use. Two primary objectives of the evaluation are to: (1) Regularly monitor, measure and analyze data in order to report on the progress of the DFC program and its grantees on program goals, and (2) providing technical assistance support to DFC grantees in effectively collecting and submitting data and in understanding the role of data in driving local coalition efforts.

Comment Request: ONDCP especially invites comments on: Whether the proposed data are proper for the functions of the agency; whether the information will have practical utility; the accuracy of ONDCP's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions; ways to enhance the quality, utility, and clarity of the information to be collected; and, ways to ease the burden on proposed respondents, including the use of automated collection techniques or other forms of information technology. Comments will be accepted for sixty days.

Dated: November 25, 2014.

Daniel S. Rader,

Deputy General Counsel.

[FR Doc. 2014–28273 Filed 11–28–14; 8:45 am]

BILLING CODE 3280–F5–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2014–0188]

Agency Information Collection Activities: Submission for the Office of Management and Budget (OMB) Review; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on August 12, 2014.

1. *Type of submission, new, revision, or extension:* Revision.

2. *The title of the information collection:* Reports Concerning Possible Non-Routine Emergency Generic Problems.

3. *Current OMB approval number:* 3150–0012.

4. *The form number if applicable:* N/A.

5. *How often the collection is required:* On occasion.

6. *Who will be required or asked to report:* Nuclear power reactor licensees, nonpower reactors, and materials applicants and licensees.

7. *An estimate of the number of annual responses:* 231

8. *The estimated number of annual respondents:* 231

9. *An estimate of the total number of hours needed annually to complete the requirement or request:* 83,100 hours annually.

10. *Abstract:* The NRC is requesting approval authority to collect information concerning possible nonroutine generic problems which would require prompt action from the NRC to preclude potential threats to public health and safety. During the conduct of normal program activities, the NRC becomes aware of an emergent event or issue that may be identified in its licensing, inspection, and enforcement programs. In addition, reportable occurrences, or unusual events, equipment failures, construction

problems, and issues discovered or raised during safety reviews are brought to the attention of the NRC through licensee reporting procedures and the safety review process. The emergent event or issue may present a situation in which the NRC does not have enough information to support regulatory decision making regarding an appropriate course of action to address the event or issue.

If the NRC determines that an event or issue may have or has the potential for an immediate impact upon public health, safety, common defense, and/or the environment, the agency will prepare a bulletin or other form of generic communication that requires licensees and/or permit holders to respond within a specified period with information that would support agency evaluation and regulatory decision making. The bulletin may request licensees and permit holders to conduct evaluations, perform tests, and provide specified information within a prescribed time frame.

The public may examine and have copied for a fee publicly-available documents, including the final supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. The OMB clearance requests are available at the NRC's Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/.* The document will be available on the NRC's home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer listed below by December 31, 2014. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Vlad Dorjets, Desk Officer, Office of Information and Regulatory Affairs (3150–0012), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be emailed to *Vladik_Dorjets@omb.eop.gov* or submitted by telephone at 202–395–7315.

The NRC Clearance Officer is Tremaine Donnell, 301–415–6258.

Dated at Rockville, Maryland, this 25th day of November, 2014.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2014–28187 Filed 11–28–14; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2014–0237]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* 10 CFR part 62, Criteria and Procedures for Emergency Access to Non-Federal and Regional Low-Level Waste Disposal Facilities.

2. *Current OMB approval number:* 3150–0143.

3. *How often the collection is required:* The collection would only be required upon application for a Commission emergency access determination when access to a non-Federal or regional Low-Level Waste Disposal facility is denied, which results in an immediate public health and safety and/or common defense and security concern.

4. *Who is required or asked to report:* Generators of low-level radioactive waste, or the Governor of a State on behalf of any generator or generators located in his or her State who are denied access to a non-Federal or regional low-level radioactive wastes and who wish to request emergency access for disposal of non-Federal or regional Low-Level Waste Disposal facility pursuant to 10 CFR part 62.

5. *The number of annual respondents:* 1 (estimate).

6. *The number of hours needed annually to complete the requirement or request:* 233 (estimate).

7. *Abstract:* 10 CFR part 62 sets out the information which must be provided to the NRC by any low-level waste generator or Governor of a State on behalf of generators seeking emergency access to an operating low-level waste disposal facility. The information is required to allow the NRC to determine if denial of disposal constitutes a serious and immediate threat to public health and safety or common defense and security. 10 CFR part 62 also provides that the Commission may grant an exemption from the requirements in this Part upon application of an interested person or upon its own initiative.

Submit, by January 30, 2015, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly-available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. The OMB clearance requests are available at the NRC's Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/.* The document will be available on the NRC's home page site for 60 days after the signature date of this notice.

Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2014–0237. You may submit your comments by any of the following methods: Electronic comments go to *http://www.regulations.gov* and search for Docket No. NRC–2014–0237. Mail comments to NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at 301–415–6258, or by email to *INFOCOLLECTS.Resource@NRC.GOV.*

Dated at Rockville, Maryland, this 24th day of November, 2014.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2014–28186 Filed 11–28–14; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Application for a License To Export Deuterium

Pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 110.70(b) ''Public Notice of Receipt of an Application,'' please take notice that the U.S. Nuclear Regulatory Commission (NRC) has received the following request for an export license. Copies of the request are available electronically through the Agencywide Documents Access and Management System and can be accessed through the Public Electronic Reading Room link *http://www.nrc.gov/reading-rm.html* at the NRC Homepage.

A request for a hearing or petition for leave to intervene may be filed within thirty days after publication of this notice in the **Federal Register** (FR). Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555; and the Executive Secretary, U.S. Department of State, Washington, DC 20520.

A request for a hearing or petition for leave to intervene may be filed with the NRC electronically in accordance with NRC's E-Filing rule promulgated in August 2007, 72 FR 49139; August 28, 2007. Information about filing electronically is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* To ensure timely electronic filing, at least five days prior to the filing deadline, the petitioner/requestor should contact the Office of the Secretary by email at *HEARINGDOCKET@NRC.GOV,* or by calling (301) 415–1677, to request a digital ID certificate and allow for the creation of an electronic docket.

In addition to a request for hearing or petition for leave to intervene, written comments, in accordance with 10 CFR 110.81, should be submitted within thirty days after publication of this notice in the FR to Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemaking and Adjudications.

The information concerning this application for an export license follows.

NRC EXPORT LICENSE APPLICATION

[Description of material]

Name of applicant; date of application; date received; application No.; docket No.	Material type	Total quantity	End use	Destination
Cambridge Isotope Laboratories, Inc.; November 6, 2014; November 7, 2014; XMAT433; 11006181.	Non-radioactive Deuterium gas, Deuterium oxide, Deuterium compounds.	10,000 kg—90% as deuterium oxide, remainder as gas and compounds.	To assist in continued scientific research; which may include identification of chemicals in reaction pathways, metabolic studies, or environmental analysis.	Republic of Korea.

Dated this 24th day of November, 2014 at Rockville, Maryland.

For the Nuclear Regulatory Commission.

David L. Skeen,

Deputy Director, Office of International Programs.

[FR Doc. 2014–28240 Filed 11–28–14; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0235]

Tribal Protocol Manual

AGENCY: Nuclear Regulatory Commission.

ACTION: Revision to guidance; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment Revision 1 of the NRC's ''Tribal Protocol Manual: Guidance for NRC Staff.'' The Tribal Protocol Manual provides internal guidance to the NRC staff on protocols to facilitate the NRC staff's engagement with Tribal governments.

DATES: Submit comments by June 1, 2015. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

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

• *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0235. Address questions about NRC dockets to Carol Gallagher; telephone: 301–287–3422; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: 3WFN–06–A44M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Patricia McGrady-Finneran, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2326; email: *Patricia.McGrady-Finneran@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2012–0235 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal rulemaking Web Site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0235.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-

available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents''* and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2012–0235 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In January 2009, the Commission directed the NRC staff to develop an internal protocol for interactions with Native American Tribal governments that allows for custom approaches to address the interests of both the NRC and the Tribal governments on a case-by-case basis (SRM–M081211). On November 5, 2009, President Obama issued a Presidential Memorandum, ''Tribal Consultation'' (74 FR 5881), that reaffirmed Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments'' (November 6, 2000; 65 FR 67249), and emphasized the importance of strengthening government-to-government relationships with Native American Tribes. In SECY–09–0180, ''U.S. Nuclear Regulatory Commission Interaction with Native American Tribes,'' dated December 11, 2009, the NRC staff reviewed its various interactions with Native American Tribes, and noted that these interactions were limited to a small number of activities under the NRC regulatory authority. At that time, the NRC staff concluded that a ''case-by-case'' approach had proved effective in interactions with Native American Tribes by allowing for custom-tailored approaches that met Commission and tribal needs, and that no formal policy was needed. The NRC staff also noted that internal guidance on protocol would further enhance the NRC staff's engagement with Native American Tribes. The internal NRC guidance, ''Tribal Protocol Manual: Guidance for NRC Employees,'' was developed and issued in March 2010. It was revised in October 2012.

III. Discussion

Section 161p. of the Atomic Energy Act of 1954, as Amended, permits the NRC to make, promulgate, issue, rescind, and amend such rules and regulations as may be necessary to carry out the purposes of this Act. This can include the development of guidance documents for implementation of the NRC's policies or provisions.

On October 12, 2012, the NRC published the ''Tribal Protocol Manual'' for public comment and requested public comments providing suggestions for a proposed tribal consultation policy statement (77 FR 62269) for a 180-day comment period. After reviewing the public comments on the October 2012 version of the Tribal Protocol Manual, the NRC revised the staff guidance. The NRC received six comment letters on the Tribal Policy Statement and protocol. Commenters included two Tribal governments, two mining associations, one inter-Tribal organization, and a Tribal college. The comments were grouped within the topics of: (1) NRC Tribal communication, (2) NRC Tribal consultation, (3) NRC Tribal resources, (4) terminology, (5) NRC map of Tribal reservations near nuclear reactors, (6) Federal-Tribal history, and (7) contemporary Tribal conditions. The NRC is making available ''Tribal Protocol Manual: Guidance for NRC Staff—Comment Responses.''

The NRC revised the Tribal Protocol Manual to define consultation for the NRC as ''meaningful and timely discussion with Tribal governments on NRC regulatory actions that have substantial direct effects on one or more Indian Tribes.'' The NRC revised the Tribal Protocol Manual to better address the unique relationship between the United States and Tribes and how the NRC exercises its trust responsibility. The NRC also made changes to the historical account of the Federal-Tribal relationship. The Tribal Protocol Manual now includes a general discussion that addresses the contributions of Treaties, policy, law, court decisions, and Executive Orders to Federal Indian law.

On August 27, 2014, the Commission directed the NRC staff (''Staff Requirements—SECY–14–0006—Tribal Consultation Policy Statement and Protocol'') to publish a draft ''Tribal Policy Statement,'' which also appears in today's **Federal Register**, and ''Tribal Protocol Manual: Guidance for NRC Staff, Revision 1'' for comment. This notice requests public comment on the ''Tribal Protocol Manual: Guidance for NRC Staff, Revision 1.'' Public comments that were received on the October 2012 version of the Tribal Protocol Manual and the NRC responses to the public comments can be found in ''Tribal Protocol Manual: Guidance for NRC Staff—Comment Responses;'' the comments received on the October 2012 version of the Tribal Protocol Manual are available through any of the methods described in Section I, ''Obtaining Information and Submitting Comments,'' of this document (i.e., through the Federal rulemaking site, NRC's ADAMS, or the NRC's PDR). The next scheduled revision of the Tribal Protocol Manual will include changes needed to conform to the final Tribal Policy Statement and will be informed by public comments on the revised Tribal Protocol Manual.

IV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS Accession No./ Web link/**Federal Register** citation
Tribal Protocol Manual: Guidance for NRC Staff, Revision 1.	ML14274A014
Tribal Protocol Manual: Guidance for NRC Staff — Comment Responses	ML14297A280
Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' November 9, 2000	65 FR 67249
Presidential Memorandum for the Heads Executive Departments and Agencies, ''Tribal Consultation,'' November 5, 2009.	74 FR 57881
SECY–09–0180, U.S. Nuclear Regulatory Commission Interaction with Native American Tribes	ML092800263
SRM–M081211, Staff Requirements—Briefing on Uranium Recovery, 9:30 a.m. and 1:30 p.m., Thursday, December 11, 2008, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance).	ML090080206
STAFF REQUIREMENTS—SECY–14–0006—TRIBAL CONSULTATION POLICY STATEMENT AND PROTOCOL	ML14240A083
Tribal Protocol Manual: Guidance for NRC Staff (October 2012)	ML12261A423

Dated at Rockville, Maryland, this 3rd day of November 2014.

For the Nuclear Regulatory Commission.

Laura A. Dudes,

Director, Division of Material Safety, States, Tribal, and Rulemaking, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2014–27324 Filed 11–28–14; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0235]

Tribal Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed policy statement; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is making available for public comment the proposed Policy Statement, ''NRC Tribal Policy Statement.'' The proposed policy statement establishes principles to be followed by the NRC to ensure effective government-to-government interactions with American Indian and Alaska Native Tribes, and to encourage and facilitate Tribal involvement in the areas over which the Commission has jurisdiction. The NRC is committed to an open and collaborative regulatory environment in the development and implementation of activities that have Tribal implications and welcomes comments as a means of fostering meaningful consultation and coordination with Indian Tribes.

DATES: Submit comments on the proposed Tribal Policy Statement by March 31, 2015. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: You may access information and submit comments related to this document by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID: NRC–2012–0235. Address questions about NRC dockets to Carol Gallagher; telephone: 301–287–3442; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch, Office of Administration, Mail Stop: 3WFN–06–44M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Michelle Ryan, telephone: 630–829–9724, email: *Michelle.Ryan@nrc.gov;* or Haimanot Yilma, telephone: 301–415–8029, email: *Haimanot.Yilma@nrc.gov;* both of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments
II. Background
III. Discussion
IV. Summary of Public Comments on the Proposed Policy Statement and NRC Staff Responses to the Comments
V. Proposed Tribal Policy Statement

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID: NRC–2012–0235 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this document by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID: NRC–2012–0235.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at: *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search*.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced. NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID: NRC–2012–0235 in the subject line of your comment submission in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include

identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Background

The purpose of this proposed Tribal Policy Statement is to establish principles to be followed by the NRC to ensure effective government-to-government interactions with Indian Tribes and to encourage and facilitate Tribal involvement in the areas over which the Commission has jurisdiction. The NRC licenses and regulates the Nation's civilian use of radioactive materials to protect public health and safety, common defense and security, and the environment under the Atomic Energy Act of 1954, as amended (AEA) (42 U.S.C. 2011). Other statutory provisions, such as the National Historic Preservation Act (NHPA) (16 U.S.C. 470) and National Environmental Policy Act (NEPA) (42 U.S.C. 4321), require Tribal consultation as part of the NRC's evaluation of agency activities during licensing actions, rulemaking, or policy development. The NRC complies with statutory provisions that require Tribal consultation, and interacts with Tribal governments on a case-by-case basis.

- In November of 2000, President Clinton issued Executive Order (E.O.) 13175, ''Consultation and Coordination with Indian Tribal Governments,'' (65 FR 67249). The Order established the legal principles below to guide agencies when forming and implementing policies with potential Tribal implications.
- The United States has a unique legal relationship with Indian Tribal governments as set forth in the Constitution of the United States, treaties, statutes, E.O.s, and court decisions. The Federal Government recognizes Indian Tribes as domestic dependent nations under its protection and has enacted statutes and promulgated regulations that establish and define a trust relationship with Indian Tribes.
- The Federal Government has recognized the right of Indian Tribes to self-government with inherent sovereign powers over their members and territory and supports Tribal sovereignty and self-determination. The United States continues to work with Indian Tribes on a government-to-government basis to address issues concerning Tribal self-government, Tribal trust resources, and Indian Tribal treaty and other rights.

E.O. 13175 states that '' 'Policies that have tribal implications' refers to regulations, legislative comments, or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.''

As an independent regulatory agency, the NRC is exempt from the requirements of EO 13175. However, in January 2001, the Commission sent correspondence to the Office of Management and Budget stating that ''in exercising its regulatory authority, this agency acts in a manner consistent with the fundamental precepts expressed in the Order [(EO 13175)].'' To that end, the Commission has adopted agency practices that ensure consultation and cooperation with Indian Tribal governments fully consistent with both President Clinton's 1994 guidance and with EO 13175'' (ADAMS Accession No. ML010260297).

In January of 2009, the Commission directed the staff to develop and implement an internal protocol for interaction with Native American Tribal Governments that would allow for custom tailored approaches to address both the NRC and Tribal interests on a case-by-case basis in a Staff Requirements Memorandum (SRM) for the December 2008 ''Briefing on Uranium Recovery,'' SRM–M081211 (ADAMS Accession No. ML090080206). The Commission also tasked the staff with preparing an assessment of the policies that other Federal agencies have developed for interactions with Tribal governments. The staff responded to this Commission direction in SECY–09–0180, ''U.S. Nuclear Regulatory Commission Interaction with Native American Tribes'' (ADAMS Accession No. ML092920384). In this document, the staff provided a protocol for NRC Tribal interaction, assessed other Federal agency Tribal policies, and examined the effectiveness of the NRC's case-by-case approach to Tribal interaction. The staff also developed the NRC Tribal Protocol Manual as an internal protocol for interacting with Tribal governments (ADAMS Accession No. ML092990559). At that time, the staff concluded that formalizing the NRC's practices would not enhance its interactions with Tribal governments.

Current NRC Practices for Interactions With Tribes

Numerous Federally recognized Tribes have an interest in public health and safety and environmental protection associated with NRC regulatory activities that include uranium recovery and nuclear power plant licensing, and radioactive material transportation and disposal, and spent fuel storage. The NRC exercises its trust relationship or fiduciary duty in the context of its authorizing statutes, including the AEA, and implements its responsibilities through assuring that Tribal members receive the same protections under regulations that are available to other persons. Under the NRC's case-by-case approach to Tribal interaction, the NRC or Tribal governments can request consultation on regulatory activities that have substantial direct Tribal implications. The NRC's policy is to consult on a government-to-government basis with Tribal governments consistent with its obligations under law and regulation [1] at the earliest stage possible in NRC regulatory actions with Tribal implications.

III. Discussion

Within the context of this discussion, the following definitions will apply unless otherwise indicated:

Consultation refers to meaningful and timely discussion with Tribal governments on NRC regulatory actions that have substantial direct effects on one or more Indian Tribes. The Consultation process may include, but is not limited to, providing for mutually agreed protocols, timely communication, coordination, cooperation, and collaboration to provide opportunities for appropriate Tribal officials or representatives to meet with NRC management or staff.

Indian Tribe means any American Indian or Alaska Native Tribe, Band, Nation, Pueblo or other organized group or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994 (25 U.S.C. 479a).

[1] The NRC's proposed policy statement is intended only to improve the internal management of the Commission, and is not intended to, and does not, grant, expand, create, or diminish any rights, benefits, or trust responsibilities, substantive or procedural, enforceable at law or in equity in any cause of action by any party against the United States, the Commission, or any person. This Tribal Policy Statement does not alter, amend, repeal, interpret, or modify Tribal sovereignty, any treaty rights of any Indian Tribes, or preempt, modify, or limit the exercise of such rights. Nothing herein shall be interpreted as amending or changing the Commission's regulations.

Regulatory Actions with Tribal Implications refers to regulations, legislative comments or proposed legislation, and other policy statements or actions including licensing and permitting that have 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.

Tribal Official means an elected, appointed, or designated official or employee of an Indian Tribe or authorized intertribal organization.

Trust Responsibility refers to a fiduciary obligation on the part of the United States to protect Tribal treaty rights, lands, assets, and resources, as well as a duty to carry out the mandates of Federal law with respect to Indian Tribes. In several cases discussing the trust responsibility, the Supreme Court has used language suggesting that it entails legal duties, moral obligations, and the fulfillment of understandings and expectations that have arisen over the entire course of the relationship between the United States and the Federally recognized Tribes. The NRC exercises its fiduciary duty in the context of its authorizing statutes including AEA, the Energy Reorganization Act of 1974, as amended, the Nuclear Waste Policy Act of 1982, as amended, the Low-Level Radioactive Waste Policy Act of 1985, the Uranium Mill Tailings Radiation Control Act of 1978, as amended, and the Energy Policy Act of 2005, as amended, and implements its responsibility by assuring that Tribal members receive the same protections under its implementing regulations that are available to other persons.

In May 2012, the Commission issued SRM–COMWDM–12–0001, ''Tribal Consultation Policy Statement and Protocol'' (ADAMS Accession No. ML121430233), directing the NRC staff to provide a proposed Policy Statement and protocol on consultation with Tribal governments. The Commission also directed staff to do the following: (1) Use the existing, ''Tribal Protocol Manual: Guidance for NRC Employees,'' and the staff's ongoing efforts outlined in SECY–09–0180 as a starting point; (2) seek input on how to improve the existing manual from the Tribes and the public; (3) ensure that the policy statement clearly articulates that the NRC's actions must be in accordance with its governing statutes and regulations; (4) ensure that the policy statement and protocol respect and reflect sensitivity between Indian Tribes who are Federally recognized and those who are not; (5) ensure that the policy statement and protocol indicate that the NRC will outreach to State-recognized Tribes on a case-by-case basis; (6) explore additional opportunities for State-recognized Tribes to participate in the NRC regulatory process; and (7) make the protocol prominently available on the NRC's public Web site. The Commission also specified that the proposed policy statement should serve as a high-level foundation for the protocol and should echo the language and spirit of the relevant Presidential Memoranda and EOs.

On October 12, 2012 (77 FR 62269), the NRC solicited public comment on its existing revised Tribal Protocol Manual and requested suggestions for the development of a proposed Policy Statement that will establish principles to be followed by the NRC to ensure effective government-to-government interactions with Indian Tribes and to encourage and facilitate involvement by Indian Tribes in the areas over which the Commission has jurisdiction. The public comment period was open for 180 days; and the NRC received six comment letters from two Tribal governments, two mining associations, one inter-Tribal organization, and a Tribal college. The staff has developed a proposed Tribal Policy Statement and revised the NRC Tribal Protocol Manual considering those comments. The Commission is currently seeking public comments on the proposed Tribal Policy Statement. The NRC is also seeking public comment on the Tribal Protocol Manual in a separate notice published concurrently in this issue of the **Federal Register**.

In 2014, the NRC intends to publish the revised Tribal Protocol Manual along with the public comments received on the prior version of that document. Once the Commission approves the final Tribal Policy Statement, the NRC will make conforming changes to the Tribal Protocol Manual, as appropriate, and reissue the Manual concurrently with the final Policy Statement. The summary of public comments to the proposed Tribal Policy Statement and the NRC responses to those comments are provided below.

IV. Summary of Public Comments and Responses to Comments

The NRC solicited suggestions regarding the development of the proposed Tribal Policy Statement by posing the following questions: (1) How can the NRC strengthen government-to-government relationships with Native American Tribes? (2) What practices have the NRC or other Federal agencies employed that have been effective in identifying Tribal interests and resolving Tribal concerns about proposed agency actions? (3) Are there specific Tribal Policy Statements from other Federal agencies that could serve as a starting point for the NRC's efforts? (4) What unique Tribal issues should the NRC be aware of as a non-landholding, regulatory agency that issues licenses under the Atomic Energy Act? Comments and responses related to these questions are listed below. Comments submitted that related to the Tribal Protocol Manual, but were useful to the development of the proposed Tribal Policy Statement, were also considered.

1. How can NRC strengthen government-to-government relationships with Native American Tribes?

Comment 1.1. Commenters suggested that the NRC may improve its government-to-government relationship with Tribes by developing a Tribal policy statement and engaging in regular dialogue with Tribes.

Response 1.1. The NRC agrees with this comment. Current staff efforts have centered on revising the NRC's Tribal Protocol Manual and developing an agency-wide Tribal Policy Statement for Commission approval.

The proposed Tribal Policy Statement recognizes the need for the NRC to seek out opportunities to engage Tribal officials regarding specific regulatory actions. The Policy Statement also recognizes that general outreach may be accomplished through NRC participation in Tribal meetings that are held by the NRC's governmental partners and through other fora. The proposed Tribal Policy Statement also underscores the NRC's commitment to its government-to-government relationship with Indian Tribes and reinforces the commitment through outreach and consultation. The proposed Tribal Policy Statement further underscores the NRC's commitment to its relationship with Indian Tribes by identifying NRC management and staff members responsible for overseeing Tribal consultation efforts.

Comment 1.2. Multiple comments centered on the importance of recognizing Tribal sovereignty and the unique legal status of Tribes as well as the Federal Trust relationship during the NRC's interaction with Tribes. Commenters noted that Tribes retain inherent sovereignty and should be considered to be governmental partners rather than ''stakeholders.'' Commenters suggested that the NRC should recognize that Tribal governments have

primary authority and responsibility for the protection of the health, safety, and welfare of their citizens and should be part of the government-to-government consultation process with respect to agency actions that may impact the citizens or lands of Indian Tribes.

Response 1.2. The NRC agrees with this comment. The Commission recognizes Tribal sovereignty and demonstrates a commitment to government-to-government relations with Federally recognized Tribes, upholding the spirit of EO 13175. Congress authorized the Federal government to regulate specified radioactive materials to protect public health and safety and common defense and security in the Atomic Energy Act of 1954. The NRC has regulatory authority over these radioactive materials in areas of exclusive Federal jurisdiction including Tribal reservations. However, the NRC exercises this regulatory authority in a manner consistent with the fundamental precepts expressed in EO 13175 and supports establishing regular and meaningful consultation and collaboration with Tribal officials in the development of Federal policies that have substantial direct effects on one or more Indian Tribes.

Comment 1.3. One comment suggested that the NRC should formally define the Federal Trust responsibility in detail.

Response 1.3. The NRC agrees with this comment with respect to defining the NRC's Federal Trust responsibility towards Indian Tribes. The proposed Tribal Policy Statement reflects the NRC's recognition of the Federal Trust relationship and the NRC's commitment to a government-to-government relationship with Federally recognized Tribes with respect to agency actions that have substantial direct effects on one or more Indian Tribes.

The NRC exercises its fiduciary duty in the context of its authorizing statutes, including the AEA, and implements any fiduciary responsibility by assuring that Tribal members receive the same protections under regulations implemented by the NRC that are available to other persons. The NRC will seek to consult with Indian Tribes on agency actions that have substantial direct effects on one or more Indian Tribes. Related staff guidance can be found in NRC Management Directive 5.1, ''Intergovernmental Consultation,'' which ensures that major interagency agreements, major organizational changes, significant rules and regulations, statements of policy, guides and standards, and major studies developed by the NRC that significantly impact Indian Tribes are prepared with appropriate involvement and meaningful consultation with Indian Tribes at the earliest possible stage (ADAMS Accession No. ML041770442).

Comment 1.4. One comment noted that the NRC should provide refreshments during meetings with Tribes.

Response 1.4. The NRC recognizes that providing refreshments during gatherings or meetings may be customary in some Native American cultures. Under Federal law, however, food and refreshments are generally considered to be personal expenses that cannot be purchased using Federal funds. The Commission must comply with Federal law pertaining to the provision of food or refreshments at meetings.

2. What practices have the NRC or other Federal agencies employed that have been effective in identifying Tribal interests and resolving Tribal concerns about proposed agency actions?

Comment 2.1. One commenter suggested that the NRC should utilize other Federal agencies in developing shared information tools to better communicate with Indian Tribes.

Response 2.1. The NRC agrees with this comment and works closely with other Federal agencies and interagency working groups on Tribal initiatives. The NRC routinely collaborates with other Federal agencies regarding Tribal consultations and has a related Memorandum of Understanding with the U.S. Bureau of Land Management. Additionally, NRC staff examined Tribal policies in place at other Federal agencies during the development of the proposed Tribal Policy Statement. The proposed Tribal Policy Statement recognizes the importance of coordinating our Tribal consultation efforts with other Federal partners.

3. Are there specific Tribal Policy Statements in other Federal agencies that could serve as a starting point for the NRC's efforts?

No commenters identified specific Federal agency policy statements that should serve as a starting point for the NRC Policy Statement. However, the NRC staff examined 15 other Federal agencies' Tribal policies and used them as a basis for developing the proposed NRC Tribal Policy Statement.

4. What unique Tribal issues should the NRC be aware of as a non-landholding, regulatory agency that issues licenses under the Atomic Energy Act?

Comment 4.1. Commenters submitted suggestions related to unique Tribal issues that the NRC should consider during the development of the proposed Tribal Policy Statement. Commenters indicated that the NRC should recognize the distinction between Federally recognized and non-Federally recognized State Tribes and noted that the NRC should consider State Tribes and other means for identifying Tribes that ratified treaties. Additionally, commenters noted that the NRC should consider the dynamics of the State and Tribal relationship, including the application of State regulations and policies to Tribal communities.

Response 4.1. The NRC agrees with this comment in part, acknowledges the unique relationship that exists between the Federal government and Federally recognized Tribes, and recognizes that this relationship is independent of any State recognition of Tribal sovereignty. The proposed Policy Statement identifies the distinction between Federal and State-recognized Tribes. This distinction is also reflected in the revised NRC Tribal Protocol Manual. However, the NRC cannot confer Federal recognition on non-Federally recognized State Tribes and defers to the Department of the Interior for such actions. With regard to State regulation and policies, typically land within the boundaries of Federally recognized Indian Tribe's Reservations is an area of exclusive Federal jurisdiction for NRC regulatory purposes.

Comment 4.2. Several comments stated the need for the NRC to understand the distinction between Tribal and Non-Tribal cultures, especially as they relate to energy development in Indian Country. Commenters suggested that the NRC should recognize that Tribal cultures vary from Tribe to Tribe and that some may place more emphasis than others on natural resources. Comments also suggested that the NRC should account for differences in culture related to the decision-making process on energy development issues, allowing for flexibility in scheduling and input from members of Indian Tribes. Commenters noted that the NRC should not only recognize Tribal laws and spiritual beliefs pertaining to the environment and natural resources but should also include discussions of risk assessment. Commenters suggested that the NRC should respect Tribal moratoriums and explicit concerns related to natural resource extraction on reservations or lands nearby. Commenters also suggested that the NRC should work with other local agencies and institutions to gain a better understanding of the complexities and uniqueness of each Indian Tribe.

Response 4.2. The NRC agrees with this comment and acknowledges that significant cultural differences may exist between Tribal and non-Tribal cultures and between the different Tribal cultures. This is reflected in staff guidance provided in the Tribal Protocol Manual, which identifies examples of cultural differences between Tribal and non-Tribal cultures and considerations for the NRC staff, including a recommendation to research Tribal history and current Tribal issues and concerns.

The NRC recognizes the importance that some Indian Tribes may place on natural resources. This is reinforced in the proposed Policy Statement, which notes that the NRC will engage in consultation with Indian Tribes on NRC regulatory actions that have substantial direct effects on one or more Indian Tribes.

The NRC recognizes that there may be differences in how the NRC staff and Tribes approach time and schedules during the decision-making process. The revised Tribal Protocol Manual has been updated to better reflect potential cultural differences with respect to agenda planning and scheduling. The NRC recognizes that Tribal elders and others knowledgeable about religious and cultural traditions can play an important role in the Tribal community during the decision-making process related to energy development and other important decisions. Chapter 2 of the Tribal Protocol Manual recognizes, ''Tribal sovereignty includes the Tribe's right to reach decisions and conduct meetings however they wish,'' and notes, ''Elders are highly respected in Tribal communities, whether or not they hold an official position.'' When the NRC engages in government-to-government consultations, it does so with designated representatives of the Tribal government, but the NRC's regulatory process allows additional opportunities for members of the Tribal community at large, along with other members of the public, to contribute comments and attend meetings.

The NRC recognizes the Tribal views of natural resources and land impact decision-making related to energy development. Chapter 3 of the revised Tribal Protocol Manual notes that, ''Some Native Americans believe that all living things are interconnected and that the spiritual and natural worlds are one. Because of this, perceived threats to their environment may be viewed as direct threats to their health, culture, and spiritual well-being.'' The Manual encourages the NRC staff to practice open communications, adaptability, and open-mindedness during interactions with Tribal members, including during risk assessment activities. With regard to Tribal moratoriums or concerns related to natural resource extraction, the NRC respects Tribal sovereignty and the Tribe's right to control the lands that are within their regulatory jurisdiction. The NRC licensees must obtain necessary permits or licenses from Federal, State, local or Tribal governments, as applicable, before operating under a NRC license. It is the NRC's practice to work closely with the Tribes, other Federal agencies and interagency working groups on Tribal initiatives to gain knowledge of Tribal cultures, beliefs, and environmental concerns.

V. Proposed Tribal Policy Statement

This section includes the proposed language in its entirety for the proposed Tribal Policy Statement, as follows.

The purpose of this proposed Tribal Policy Statement is to set forth principles to be followed by the U.S. Nuclear Regulatory Commission (NRC) to ensure effective

government-to-government interactions with American Indian and Alaska Native Tribes and to encourage and facilitate Tribal involvement in the areas over which the NRC has jurisdiction. It seeks to provide agency-wide principles to achieve consistency but also encourage custom-tailored approaches to consultation and coordination that reflect the circumstances of each situation and the preference of each Tribal government. It is the NRC's expectation that all program and regional office consultation and coordination practices will be consistent and adhere to the Tribal Policy Statement. This Tribal Policy Statement is based on the United States Constitution, treaties, statutes, Executive Orders (EOs), judicial decisions, and the unique relationship between Indian Tribes and the Federal government.[2]

The following principles shall guide the NRC's interaction with Indian Tribes:

[2] This Tribal Policy Statement is intended only to improve the internal management of the Commission, and is not intended to, and does not, grant, expand, create, or diminish any rights, benefits, or trust responsibilities, substantive or procedural, enforceable at law or in equity in any cause of action by any party against the United States, the Commission, or any person. This Tribal Policy Statement does not alter, amend, repeal, interpret, or modify Tribal sovereignty, any treaty rights of any Indian Tribes, or preempt, modify, or limit the exercise of such rights. Nothing herein shall be interpreted as amending or changing the Commission's regulations.

1. The NRC Recognizes the Federal Trust Relationship and Will Uphold Its Trust Relationship With Indian Tribes

As an independent agency of the Federal government, the NRC shares the unique trust relationship with, and responsibility to, Indian Tribes. At the same time, the NRC's actions must be in accordance with its authorizing statutes and regulations. The NRC shall respect Indian Tribal self-government and sovereignty, will honor Tribal rights, and meet responsibilities that arise from the unique relationship between the Federal government and Indian Tribal governments.

2. The NRC Recognizes and Is Committed to a Government-to-Government Relationship With Indian Tribes

The NRC recognizes the right of each Indian Tribe to self-governance and supports Tribal sovereignty and self-determination. The NRC recognizes Tribal governments as dependent domestic sovereign nations, independent from State governments, with separate and distinct authorities.

3. The NRC Will Conduct Outreach to Indian Tribes

The NRC will consult and coordinate with Indian Tribes, as appropriate, related to its regulatory actions with Tribal implications and will seek additional opportunities for general outreach. The NRC will participate in national and regional Tribal conferences and summits hosted by Federal agencies and Tribal organizations, and will seek Tribal representation in NRC meetings and advisory committees concerning NRC regulatory actions that have substantial direct effects on one or more Indian Tribes.

4. The NRC Will Engage in Timely Consultation

The NRC will provide timely notice to, and consult with, Tribal governments on NRC's regulatory actions that have substantial direct effects on one or more Indian Tribes. Tribal officials may request that the NRC engage in government-to-government consultation with them on matters that have not been identified by the NRC to have substantial direct effects on one or more Indian Tribes. The NRC will make efforts to honor such requests, taking into consideration the nature of the activity at issue, past consultation efforts, available resources, timing issues, and other relevant factors.

The NRC will establish early communications and begin consultation at the earliest permissible stage, as appropriate. The NRC will consult in

good faith throughout the agency decision-making process and develop and maintain effective communication, coordination, and cooperation with Indian Tribes. The NRC representative for consultations with Tribal officials or representatives will be of an appropriate rank of NRC representatives and level of interaction commensurate with the circumstances. The appropriate level of interaction will be determined by past and current practices, continuing dialogue between NRC and Tribal governments, and program office consultation procedures.

5. The NRC Will Coordinate With Other Federal Agencies

When the Commission's action involves other Federal agencies, the NRC will perform its Tribal consultation jointly with other Federal agencies, as appropriate.

6. The NRC Will Encourage Participation by State-Recognized Tribes

The NRC recognizes the distinction between Indian Tribes who are Federally recognized and those who are not. The NRC will outreach to States to identify the appropriate State-recognized Tribes to invite to participate in its regulatory process, including opportunities related to rulemaking, hearings, licensing, decommissioning, and enforcement.

Designated Official and Tribal Liaisons

The Deputy Executive Director for Materials, Waste, Research, State, Tribal and Compliance Programs serves as the NRC's designated official for Tribal consultations.[3] The designated official shall ensure that agency program personnel have considered the Tribal implications related to their responsibilities within the NRC's scope of jurisdiction and shall facilitate meaningful and timely consultation and coordination concerning the development, administration, and enforcement of NRC's regulatory actions that have substantial direct effects on one or more Indian Tribes.

The designated official shall be supported by staff who have functional responsibility to serve as intergovernmental liaisons to Indian Tribes, under NRC Management Directive 5.1. These NRC Tribal liaisons will facilitate government-to-government consultation by serving as the agency's primary points of contact for Indian Tribes, coordinating with the appropriate office or personnel regarding programmatic inquiries, and facilitating the appropriate level of communication and exchange of information between Tribal officials and NRC staff. The Tribal liaisons shall also educate NRC staff about Tribal issues including cultural sensitivity and the Federal Trust Relationship. The designated official shall have the authority to delegate tasks to NRC Tribal liaisons as he/she deems fit.

[3] In 2006, the Commission created the position of Deputy Executive Director for Materials, Waste, Research, State, Tribal and Compliance Programs (SECY–06–0125, ''Proposed Reorganization of the Offices of Nuclear Material Safety and Safeguards and State and Tribal Programs'' (ADAMS Accession No. ML061950452)). The position includes different responsibilities, including that of the Commission's designated official for Tribal consultations.

VI. Procedural Requirements

Paperwork Reduction Act Statement

This Policy Statement does not contain new or amended information collection requirements and, therefore, is not subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request protocol for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

Dated at Rockville, Maryland, this 10th day of November, 2014.

For the Nuclear Regulatory Commission.

Rochelle C. Bavol,

Acting, Secretary of the Commission.

[FR Doc. 2014–27325 Filed 11–28–14; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Microsatellite Technologies for Civil Earth Observations

ACTION: Notice of Request for Information (RFI).

SUMMARY: The purpose of this Request for Information (RFI) is to solicit input from interested parties on: (1) The current and near-term state of microsatellite technologies, and (2) whether microsatellite systems will be capable of meeting current and future civil Earth-observing needs.

Public input provided in response to this RFI will inform the Office of Science and Technology Policy (OSTP) as to the state of technologies associated with microsatellites to meet the Nation's civil Earth observational requirements.

DATES: Responses must be received by 30 days from publication date to be considered.

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

- Downloadable form/email: To aid in information collection and analysis, OSTP encourages responders to fill out the downloadable form located at *http://www.whitehouse.gov/sites/default/files/microsites/ostp/microsat_rfi_final.pdf* and email that form, as an attachment, to *EarthObsStudy@OSTP.gov.* Please include ''Microsatellite Technologies for Civil Earth Observations'' in the subject line of the message.
- Fax: (202) 456–6071.
- Mail: Office of Science and Technology Policy, 1650 Pennsylvania Avenue NW., Washington, DC 20504. Information submitted by postal mail should allow ample time for processing.

Response to this RFI is voluntary. Respondents need not respond to each section of the RFI; however, they should clearly identify those sections to which they are responding by listing the corresponding number for each point listed below. Respondents *must* mark their responses as ''Business Confidential'' if responses contain information that is business proprietary, or commercial confidential information. OSTP will protect such information consistent with applicable law.

Please note that the U.S. Government will not pay for response preparation, or for the use of any information contained in the response.

FOR FURTHER INFORMATION CONTACT: Timothy Stryker, 202–419–3471, *tstryker@ostp.eop.gov,* OSTP.

SUPPLEMENTARY INFORMATION:

Background

In recent decades, the United States' Earth-observing capacity has grown in scale and complexity, with multiple Federal agencies collecting information about the state of the Earth system. Earth observation systems consist of sensing elements that directly or indirectly collect observations of the Earth, measure environmental parameters, or survey biological or other Earth resources (such as land surface, biosphere, solid Earth, atmosphere, and oceans). The platforms carrying these sensing elements may be mobile or fixed, and are space-based, airborne, terrestrial, freshwater, or marine-based.

Space-based observation systems have been used for decades to collect critical information used by the civil Earth observation community. The high vantage point afforded by Earth orbit provides the opportunity to conduct

observations covering broad areas, over long periods with frequent revisit rates. Satellite platforms can be costly, and technology improvements are implemented on lengthy timeframes. As microsatellite technology improves, the cost of collecting sustained and scientific observations from space may decrease, not only reducing costs for current observations, but potentially enabling additional missions.

In 2013, the National Science and Technology Council (NSTC) released a National Strategy for Civil Earth Observations (*http://www.whitehouse.gov/sites/default/files/microsites/ostp/nstc_2013_earthobsstrategy.pdf*) outlining a policy framework organized by Societal Benefit Areas (SBAs) to enable stable, continuous, and coordinated global Earth-observation capabilities for the benefit of society. Societal benefits accrue from Earth observations that inform scientific research, policy, and decision-making. SBAs are interconnected at local, regional, national, and international scales, and include scientific research, economic activities, and environmental and social domains.

Many SBAs involve critical government functions, such as the continuity of national government and the protection of life and property. The NSTC framework enabled the development of a National Plan for Civil Earth Observations informed by a government-wide assessment of the impact of more than 350 Earth observation systems.

The National Plan for Civil Earth Observations (*http://www.whitehouse.gov/sites/default/files/microsites/ostp/NSTC/2014_national_plan_for_civil_earth_observations.pdf*) published in July 2014, lists the highest priority measurement groups for observations as:

- Weather and seasonal climate monitoring and prediction, which characterize phenomena such as precipitation, storms, wind, floods, sea state, drought, wildfires, ice, air quality (including ozone), and weather risks to human health and transportation.
- Dynamic land-surface monitoring and characterization to support food and water security, water availability and quality, fire detection and suppression, human health, forestry, soil characterization (including soil moisture), hazards mapping and response, and natural-resource management.
- Elevation and geo-location to support food and water security, hazard and risk mapping, and natural-resource management.
- Water level and flow to support coastal inundation and inland flooding, water availability, hydropower management, transportation, human health, water equivalent of snow, and tsunami hazard preparedness.

In addition to these highest priority measurement areas, the National Plan (*http://www.whitehouse.gov/sites/default/files/microsites/ostp/NSTC/2014_national_plan_for_civil_earth_observations.pdf*) specifies additional categories of measurement areas that are also important for sustained observations for public services. These categories include:

- Ecosystem and biodiversity resource surveys for terrestrial, freshwater, and marine ecosystems, including fisheries and wildlife management;
- Environmental-quality monitoring, specifically disease-vector surveillance, water quality, and air quality associated with changes in atmospheric composition, including particulate matter and short-lived climate pollutants;
- Geo-hazard monitoring for Earthquakes, volcanoes, landslides, regional and local subsidence (*e.g.,* sinkholes), inundation, and tsunamis; and
- Space-weather monitoring of geomagnetic storms, sunspots, solar flares, associated x-ray and ultraviolet emissions, solar wind (including coronal mass ejection), solar energetic particles, traveling ionosphere disturbances, and associated changes of the Earth's geomagnetic field and ionosphere for their impact on human activities.

The National Plan also describes the following measurement categories as essential to the Federal government's research objectives:

- Atmospheric state, including measurements of temperature, pressure, humidity, wind, and ozone at the accuracy required for long-term climate research, and, as appropriate, to improve short and medium-range weather forecasting;
- Cryosphere, including measurements of ice sheets, glaciers, permafrost, snow, and sea ice extent and thickness;
- Earth's energy budget, including total solar irradiance and Earth's radiation budget, and the reflectance and scattering properties of clouds, aerosols, and greenhouse gases, specifically for understanding Earth's sensitivity to climate change;
- Extremes, including specific and routine observations for the study of extreme temperatures, drought, precipitation, and wind;
- Geo-hazard research, including monitoring land-surface deformation to better understand regional and local disaster potential and effects, and the monitoring of phenomena that precede natural disasters (such as seismic, stress, strain, geochemical, and temperature changes);
- Greenhouse gas emissions and concentrations, including understanding sources and sinks of greenhouse gases, as well as changes in long-lived greenhouse gas and short-lived climate pollutant concentrations over time;
- Integrated geophysical and biosphere characterization (terrestrial, freshwater, and marine), including long-term dynamics to understand ecosystem change and biogeochemical processes (particularly the carbon cycle);
- Ocean state, including observations of sea levels, temperature, salinity, pH, alkalinity, currents and characteristics of marine ecosystems;
- Space weather, including long-term understanding of the Earth-Sun relationship, solar dynamics, and the drivers of space-weather impacts at the Earth's surface (such as coupling between space weather and geomagnetic storms); and
- Water cycle, including the analysis of droughts, floods, and water availability (precipitation, soil moisture, snow-water equivalent, evapotranspiration, groundwater, surface water, and runoff).

Societal Benefit Areas

(*http://www.whitehouse.gov/sites/default/files/microsites/ostp/nstc_2013_earthobsstrategy.pdf*)

- Agriculture and Forestry: Supporting sustainable agriculture and forestry.
- Biodiversity: Understanding and conserving biodiversity.
- Climate: Understanding, assessing, predicting, mitigating, and adapting to climate variability and related global change.
- Disasters: Reducing loss of life, property, and ecosystem damage from natural and human-induced disasters.
- Ecosystems (Terrestrial and Freshwater): Improving the management and protection of terrestrial and freshwater ecosystems.
- Energy and Mineral Resources: Improving the identification and management of energy and mineral resources.
- Human Health: Understanding environmental factors affecting human health and well-being.
- Ocean and Coastal Resources and Ecosystems: Understanding and protecting ocean, coastal, and Great

Lakes populations and resources (including fisheries, aquaculture, and marine ecosystems).

• Space Weather: Understanding, assessing, predicting, and mitigating the effects of space weather on technological systems (including satellites, power grids, communications, and navigation).

• Transportation: Improving the safety and efficiency of all modes of transportation (including air, highway, railway, and marine).

• Water Resources: Improving water resource management through better understanding and monitoring of the water cycle.

• Weather: Improving weather information, forecasting, and warning.

• Reference Measurements: Improving reference measurements—the underpinnings of all the SBAs—and the fundamental measurement systems and standards supporting them (such as geodesy, bathymetry, topography, and geolocation).

OSTP invites you to submit public comments (limit 5 pages) on the technical feasibility of developing microsatellites that can be deployed at equal or lower cost compared to current satellites to meet the sustained missions of the civil Earth observation community. For the purposes of this study, OSTP considers microsatellites as having a mass of less than 100 kg. In your written response, please identify the number of each topic as you address it.

OSTP welcomes public input on the following topics:

1. Identify the measurement categories highlighted in the National Plan for Civil Earth Observations relevant to your mission;

2. Technical near-term (1–5 years) capabilities of microsatellite system(s) related to Earth observations capabilities as defined above;

3. Reliability, system lifetime, and maintainability;

4. Launch requirements including planned launch options (rideshare, microsatellite launch companies, etc.), if they exist;

5. Current technical limitations on microsatellites for operational Earth observing missions; and

6. Broad estimates of development, launch and operational costs of specific systems.

Ted Wackler,

Deputy Chief of Staff and Assistant Director.

[FR Doc. 2014–28178 Filed 11–28–14; 8:45 am]

BILLING CODE 3270–F5–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31347; File No. 812–14331]

MUFG Union Bank, N.A.; Notice of Application

November 24, 2014.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under Section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from certain requirements of Rule 3a–7(a)(4)(i) under the Act.

SUMMARY: *Summary of Application:* Applicant requests an order that would permit an issuer of asset-backed securities (''ABS'') that is not registered as an investment company under the Act in reliance on Rule 3a–7 under the Act (an ''Issuer'') to appoint the applicant as a trustee in connection with the Issuer's ABS when the applicant is affiliated with an underwriter for the Issuer's ABS.

Applicant: MUFG Union Bank, N.A.

DATES: *Filing Dates:* The application was filed on July 11, 2014 and amended on October 3, 2014 and October 10, 2014.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 19, 2014 and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: The Commission: Brent J. Fields, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.
Applicant: MUFG Union Bank, N.A., 445 S. Figueroa Street, Suite 1203, Los Angeles, CA 90071.

FOR FURTHER INFORMATION CONTACT: Rochelle Kauffman Plesset, Senior Counsel, at (202) 551–6840, or Nadya Roytblat, Assistant Chief Counsel at (202) 551–0825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicant's Representations

1. The applicant is a wholly-owned indirect subsidiary of Mitsubishi UFJ Financial Group, Inc. (MUFG).[1] MUFG is a global financial services organization that offers a broad range of banking, trust, and securities services to individuals and entities around the world. The applicant is frequently selected to act as trustee in connection with ABS issued by Issuers.

2. An ABS transaction typically involves the transfer of assets by a seller, usually by a ''sponsor,'' to a bankruptcy remote special purpose corporate or trust entity that is established for the sole purpose of holding the assets and issuing ABS to investors (an ''ABS Transaction''). Payments of interest and principle on the ABS depend primarily on the cash flow generated by the pool of assets owned by the Issuer.

3. The parties to an ABS Transaction enter into several transaction agreements that provide for the holding of the assets by the Issuer and define the rights and responsibilities of the parties to the transaction (''Transaction Documents''). The operative Transaction Document governing the trustee is referred to herein as the ''Agreement.''

4. The sponsor of an ABS Transaction assembles the pool of assets by purchasing or funding them, describes them in the offering materials, and retains the underwriter to sell interests in the assets to investors. The sponsor determines the structure, drafts the documents, and prices the ABS Transaction. The sponsor selects the other parties to the ABS Transaction, including the underwriter, the servicer, and the trustee.

5. The servicer, either directly or through subservicers, manages the assets held by the Issuer. The servicer typically collects the income from the assets and remits the income to the

[1] The applicant also requests that the order apply to an Issuer's future appointment of any other entity controlling, controlled by, or under common control (as defined in Section 2(a)(9) of the Act) with the applicant as a trustee in connection with an Issuer's ABS. The applicant represents that any other entity intending to rely on this relief will comply with the terms and conditions of the application. Any existing entity currently intending to rely on the requested order has been named as an applicant.

trustee. The trustee uses the income, as instructed by the servicer and as provided by the Agreement, to pay interest and principal on the ABS, to fund reserve accounts and purchases of additional assets, and to make other payments including fees owed to the trustee and other parties to the ABS Transaction.

6. The sponsor of an ABS Transaction selects the trustee and other participants in the transaction. In selecting a trustee, the sponsor generally seeks to obtain customary trust administrative and related services for the Issuer at minimal cost. In some instances, other parties to an ABS Transaction may provide recommendations to a sponsor about potential trustees. An underwriter for an ABS Transaction also may provide advice to the sponsor about trustee selection based on the underwriter's knowledge of the pricing and expertise offered by a particular trustee in light of the contemplated transaction.

7. If an underwriter affiliated with the applicant recommends a trustee to a sponsor, both the underwriter's recommendation and any selection of the applicant by the sponsor will be based upon customary market considerations of pricing and expertise, among other things, and the selection will result from an arms-length negotiation between the sponsor and the applicant. The applicant will not price its services as trustee in a manner designed to facilitate its affiliate being named underwriter.

8. The trustee's role in an ABS Transaction is specifically defined by the Agreement, and under the Agreement the trustee is not expected or required to perform discretionary functions. The responsibilities of the trustee as set forth in the Agreement are narrowly circumscribed and limited to those expressly accepted by the trustee. The trustee negotiates the provisions applicable to it directly with the sponsor and is then appointed by, and enters into the Agreement with, the Issuer.

9. The trustee usually becomes involved in an ABS Transaction after the substantive economic terms have been negotiated between the sponsor and the underwriters. The trustee does not monitor any service performed by, or obligation of, an underwriter, whether or not the underwriter is affiliated with the trustee. In the unlikely event that the applicant, in acting as trustee to an Issuer for which an affiliate acts as underwriter, becomes obligated to enforce any of the affiliated underwriter's obligations to the Issuer, the applicant will resign as trustee for the Issuer consistent with the requirements of Rule 3a–7(a)(4)(i). In such an event, the applicant will incur the costs associated with the Issuer's procurement of a successor trustee.

10. The sponsor selects one or more underwriters to purchase the Issuer's ABS and resell them or to privately place them with buyers obtained by the underwriter. The sponsor enters into an underwriting agreement with the underwriter that sets forth the responsibilities of the underwriter with respect to the distribution of the ABS and includes representations and warranties regarding, among other things, the underwriter and the quality of the Issuer's assets. The obligations of the underwriter under the underwriting agreement are enforceable against the underwriter only by the sponsor.

11. The underwriter may assist the sponsor in the organization of an Issuer by providing advice, based on its expertise in ABS Transactions, on the structuring and marketing of the ABS. This advice may relate to the risk tolerance of investors, the type of collateral, the predictability of the payment stream, the process by which payments are allocated and down-streamed to investors, the way that credit losses may affect the trust and the return to investors, whether the collateral represents a fixed set of specific assets or accounts, and the use of forms of credit enhancements to transform the risk-return profile of the underlying collateral. Any involvement of an underwriter in the organization of an Issuer that occurs is limited to helping determine the assets to be pooled, helping establish the terms of the ABS to be underwritten, and providing the sponsor with a warehouse line of credit with which to purchase the pool assets.

12. An underwriter may provide advice to a sponsor regarding the sponsor's selection of a trustee for the Issuer. However, an underwriter's role in structuring a transaction would not extend to determining the obligations of a trustee, and the underwriter is not a party to the Agreement or to any of the Transaction Documents. Except for arrangements involving credit or credit enhancement for an Issuer or remarketing agent activities, the underwriter typically has no role in the operation of the Issuer after its issuance of securities. The applicant represents that although an underwriter typically may provide credit or credit enhancement for an Issuer or engage in remarketing agent activities, an underwriter affiliated with the applicant will not provide or engage in such activities.

Applicant's Legal Analysis

1. Rule 3a–7 excludes from the definition of investment company under Section 3(a) of the Act an Issuer that meets the conditions of the rule. One of Rule 3a–7's conditions, set forth in paragraph (a)(4)(i), requires that the Issuer appoint a trustee that is not affiliated with the Issuer or with any person involved in the organization or operation of the Issuer (the ''Independent Trustee Requirement''). Rule 3a–7(a)(4)(i) therefore prohibits an Issuer from appointing a trustee that is affiliated with an underwriter.

2. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction or any class or classes of persons, securities or transactions from any provision of the Act, or from any rule thereunder, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

3. Applicant requests exemptive relief under Section 6(c) of the Act from Rule 3a–7(a)(4)(i) under the Act to the extent necessary to permit an Issuer to appoint the applicant as a trustee to the Issuer when the applicant is affiliated with an underwriter involved in the organization of the Issuer. Applicant submits that the requested exemptive relief from the Independent Trustee Requirement is necessary and appropriate in the public interest and is consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act due to changes in the banking industry, due to the timing and nature of the roles of the trustee and the underwriter in ABS Transactions, and because the requested relief is consistent with the policies and purposes underlying the Independent Trustee Requirement and Rule 3a–7 in general.

4. Applicant states that when Rule 3a–7 was proposed in 1992, virtually all trustees were unaffiliated with the other parties involved in an ABS Transaction. Applicant states that consolidation within the banking industry, as well as economic and other business factors, has resulted in a significant decrease in the number of bank trustees providing services to Issuers. Applicant also states that bank consolidation has been accompanied by the expansion of banks into investment banking, including the underwriting of ABS Transactions. Applicant further states that due to these banking industry changes, most trustees that provide services to Issuers,

including the applicant, have affiliations with underwriters to Issuers. Applicant states that, as a result, when an affiliate of the applicant is selected to underwrite ABS in an ABS Transaction, Rule 3a–7(a)(4)(i)'s Independent Trustee Requirement generally prevents applicant from serving as trustee for the Issuer. Applicant states that the Independent Trustee Requirement imposes an unnecessary regulatory limitation on trustee selection and causes market distortions by leading to the selection of trustees for reasons other than customary market considerations of pricing and expertise. This result is disadvantageous to the ABS market and to ABS investors.

5. Applicant submits that due to the nature and timing of the roles of the trustee and the underwriter, applicant's affiliation with an underwriter would not result in a conflict of interest or possibility of overreaching that could harm investors. Applicant states that the trustee's role begins with the Issuer's issuance of its securities, and the trustee performs its role over the life of the Issuer. Applicant states that, in contrast, the underwriter is chosen early in the ABS Transaction process, may help to structure the ABS Transaction, distributes the Issuer's securities to investors, and generally has no role subsequent to the distribution of the Issuer's securities. Applicant further states that an ABS trustee does not monitor the distribution of securities or any other activity performed by underwriters and there is no opportunity for a trustee and an affiliated underwriter to act in concert to benefit themselves at the expense of holders of the ABS either prior to or after the closing of the ABS Transaction.

6. Applicant states that the trustee's role is narrowly defined, and that the trustee is neither expected nor required to exercise discretion or judgment except after a default in the ABS transaction, which rarely occurs. Applicant states that the duties of a trustee after a default are limited to enforcing the terms of the Agreement for the benefit of debt holders as a ''prudent person'' would enforce such interests for his own benefit. Applicant further states that the trustee of the Issuer has virtually no discretion to pursue anyone in any regard other than preserving and realizing on the assets. In any event, Applicant states that any role taken by the Trustee in the event of a default would occur after the underwriter has terminated its role in the transaction.

7. Applicant submits that the concerns underlying the Independent Trustee Requirement are not implicated if the trustee for an Issuer is independent of the sponsor, servicer, and credit enhancer for the Issuer, but is affiliated with an underwriter for the Issuer, because in that situation no single entity would act in all capacities in the issuance of the ABS and the operation of an Issuer. Applicant states that applicant would continue to act as an independent party safeguarding the assets of any Issuer regardless of an affiliation with an underwriter of the ABS. Applicant submits that the concern that affiliation could lead to a trustee monitoring the activities of an affiliate also is not implicated by a trustee's affiliation with an underwriter, because, in practice, a trustee for an Issuer does not monitor the distribution of securities or any other activity performed by underwriters. Applicant further states that the requested relief would be consistent with the broader purpose of Rule 3a–7 of not hampering the growth and development of the ABS market, to the extent consistent with investor protection.

8. Applicant states that the conditions set forth below provide additional protections against conflicts and overreaching. For example, the conditions ensure that the Applicant will continue to act as an independent party safeguarding the assets of an Issuer regardless of an affiliation with the underwriter of the ABS and would not allow the underwriter any greater access to the assets, or cash flows derived from the assets, of the Issuer than if there were no affiliation.

Applicant's Conditions

The applicant agrees that any order granting the requested relief will be subject to the following conditions:

1. The applicant will not be affiliated with any person involved in the organization or operation of the Issuer in an ABS Transaction other than the underwriter.

2. The applicant's relationship to an affiliated underwriter will be disclosed in writing to all parties involved in an ABS Transaction, including the rating agencies and the ABS holders.

3. An underwriter affiliated with the applicant will not be involved in the operation of an Issuer, and its involvement in the organization of an Issuer will extend only to determining the assets to be pooled, assisting in establishing the terms of the ABS to be underwritten, and providing the sponsor with a warehouse line of credit with which to purchase the pool assets.

4. An affiliated person of the applicant, including an affiliated underwriter, will not provide credit or credit enhancement to an Issuer if the applicant serves as trustee to the Issuer.

5. An underwriter affiliated with the applicant will not engage in any remarketing agent activities, including involvement in any auction process in which ABS interest rates, yields, or dividends are reset at designated intervals in any ABS Transaction from which the applicant serves as trustee to the Issuer.

6. All of an affiliated underwriter's contractual obligations pursuant to the underwriting agreement will be enforceable by the sponsor.

7. Consistent with the requirements of Rule 3a–7(a)(4)(i), the applicant will resign as trustee for the Issuer if applicant becomes obligated to enforce any of an affiliated underwriter's obligations to the Issuer.

8. The applicant will not price its services as trustee in a manner designed to facilitate its affiliate being named underwriter.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–28174 Filed 11–28–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–31344]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

November 21, 2014.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of November 2014. A copy of each application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on December 19, 2014, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act,

hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: The Commission: Brent J. Fields, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

FOR FURTHER INFORMATION CONTACT: Diane L. Titus at (202) 551–6810, SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE., Washington, DC 20549–8010.

Cushing Funds Trust

[File No. 811–22428]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to corresponding series of MainStay Funds Trust, and on July 7, 2014, made distributions to its shareholders based on net asset value. Expenses of $822,606 incurred in connection with the reorganization were paid by Cushing Asset Management, L.P., applicant's investment adviser, and New York Life Investment Management LLC, the surviving fund's investment adviser.

Filing Date: The application was filed on October 27, 2014.

Applicant's Address: 8117 Preston Rd., Suite 440, Dallas, TX 75225.

Lattice Strategies, LLC

[File No. 811–23001]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant states the filings on Form N–8A and N–1A made under applicant's file number were inadvertent and were intended instead to be filed under the file number of Lattice Strategies Trust.

Filing Date: The application was filed on October 24, 2014.

Applicant's Address: One Embarcadero Center, 23rd Floor, San Francisco, CA 94111.

Oceanstone Fund

[File No. 811–21930]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On August 29, 2014, applicant made a liquidating distribution to its shareholders, based on net asset value. Applicant incurred no expenses in connection with the liquidation.

Filing Date: The application was filed on October 29, 2014.

Applicant's Address: PO Box 130982, Carlsbad, CA 92013.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–28175 Filed 11–28–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73676; File No. SR–NASDAQ–2014–105]

Self-Regulatory Organizations; The NASDAQ Stock Market, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Rebates in Penny Pilot Options

November 24, 2014.

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 November 10, 2014, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASDAQ. 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

NASDAQ proposes to modify Chapter XV, entitled ''Options Pricing,'' at Section 2 governing pricing for NASDAQ members using the NASDAQ Options Market (''NOM''), NASDAQ's facility for executing and routing standardized equity and index options. Specifically, NOM proposes to amend certain Penny Pilot Options[3] rebates currently applicable to Customers,[4] Professionals[5] and NOM Market Makers.[6]

The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Penny Pilot was established in March 2008 and in October 2009 was expanded and extended through December 31, 2014. *See* Securities Exchange Act Release Nos. 57579 (March 28, 2008), 73 FR 18587 (April 4, 2008) (SR–NASDAQ–2008–026) (notice of filing and immediate effectiveness establishing Penny Pilot); 60874 (October 23, 2009), 74 FR 56682 (November 2, 2009) (SR–NASDAQ–2009–091) (notice of filing and immediate effectiveness expanding and extending Penny Pilot); 60965 (November 9, 2009), 74 FR 59292 (November 17, 2009) (SR–NASDAQ–2009–097) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot); 61455 (February 1, 2010), 75 FR 6239 (February 8, 2010) (SR–NASDAQ–2010–013) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot); 62029 (May 4, 2010), 75 FR 25895 (May 10, 2010) (SR–NASDAQ–2010–053) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot); 65969 (December 15, 2011), 76 FR 79268 (December 21, 2011) (SR–NASDAQ–2011–169) (notice of filing and immediate effectiveness extension and replacement of Penny Pilot); 67325 (June 29, 2012), 77 FR 40127 (July 6, 2012) (SR–NASDAQ–2012–075) (notice of filing and immediate effectiveness and extension and replacement of Penny Pilot through December 31, 2012); 68519 (December 21, 2012), 78 FR 136 (January 2, 2013) (SR–NASDAQ–2012–143) (notice of filing and immediate effectiveness and extension and replacement of Penny Pilot through June 30, 2013); 69787 (June 18, 2013), 78 FR 37858 (June 24, 2013) (SR–NASDAQ–2013–082) (notice of filing and immediate effectiveness and extension and replacement of Penny Pilot through December 31, 2013); 71105 (December 17, 2013), 78 FR 77530 (December 23, 2013) (SR–NASDAQ–2013–154) (notice of filing and immediate effectiveness and extension and replacement of Penny Pilot through June 30, 2014); and 79 FR 31151 (May 23, 2014), 79 FR 31151 (May 30, 2014) (SR–NASDAQ–2014–056) ((notice of filing and immediate effectiveness and extension and replacement of Penny Pilot through December 31, 2014). *See also* NOM Rules, Chapter VI, Section 5.

[4] The term ''Customer'' applies to any transaction that is identified by a Participant for clearing in the Customer range at The Options Clearing Corporation (''OCC'') which is not for the account of broker or dealer or for the account of a ''Professional'' (as that term is defined in Chapter I, Section 1(a)(48)).

[5] The term ''Professional'' means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s) pursuant to Chapter I, Section 1(a)(48). All Professional orders shall be appropriately marked by Participants.

[6] The term ''NOM Market Maker'' means a Participant that has registered as a Market Maker on NOM pursuant to Chapter VII, Section 2, and must also remain in good standing pursuant to Chapter VII, Section 4. In order to receive NOM Market Maker pricing in all securities, the Participant must be registered as a NOM Market Maker in at least one security.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

NASDAQ proposes to modify Chapter XV, entitled ''Options Pricing,'' at Section 2(1) governing the rebates and fees assessed for option orders entered into NOM. The Exchange proposes to amend certain qualifications related to Customer and Professional Penny Pilot Options Rebates to Add Liquidity tiers to offer Participants a greater opportunity to earn Customer and Professional rebates. The Exchange also proposes to modify NOM Market Maker Penny Pilot Options Rebates to Add Liquidity to offer additional rebate opportunities. The Exchange believes that additional rebate opportunities will attract additional order flow to the Exchange to the benefit of all market participants.

Customer and Professional Rebates To Add Liquidity

Today, the Exchange offers tiered Penny Pilot Options Rebates to Add Liquidity to Customers and Professionals based on various criteria with rebates ranging from $0.20 to $0.48 per contract. Participants may qualify for Customer and Professional Penny Pilot Options Rebates to Add Liquidity in Tiers 1–5 and Tier 8 by adding a certain amount of Customer and/or Professional liquidity in Penny Pilot Options or Non-Penny Pilot Options as specified by each tier.[7] The Exchange is proposing to amend these tiers and permit Participants to add Customer, Professional, Firm,[8] Non-NOM Market Maker [9] and/or Broker-Dealer [10] liquidity in Penny Pilot Options and/or Non-Penny Pilot Options in order to qualify for the Customer and/or Professional Penny Pilot Options Rebates to Add Liquidity in Tiers 1–5 and Tier 8.

Tier 1 currently offers Participants that add Customer and/or Professional liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of up to 0.10% of total industry customer equity and ETF option average daily volume (''ADV'') contracts per day in a month a $0.20 per contract rebate. The Exchange is proposing to amend Tier 1 to provide that Participants that add Customer, Professional, *Firm, Non-NOM Market Maker and/or Broker-Dealer* liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of up to 0.10% of total industry customer equity and ETF option average daily volume (''ADV'') contracts per day in a month would continue to receive a $0.20 per contract rebate.

Tier 2 currently offers Participants that add Customer and/or Professional liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.10% to 0.20% of total industry customer equity and ETF option ADV contracts per day in a month a $0.25 per contract rebate. The Exchange is proposing to amend Tier 2 to provide that Participants that add Customer, Professional, *Firm, Non-NOM Market Maker and/or Broker-Dealer* liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.10% to 0.20% of total industry customer equity and ETF option ADV contracts per day in a month would continue to receive a $0.25 per contract rebate.

Tier 3 currently offers Participants that add Customer and/or Professional liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.20% to 0.30% of total industry customer equity and ETF option ADV contracts per day in a month a $0.42 per contract rebate. The Exchange is proposing to amend Tier 3 to provide that Participants that add Customer, Professional, *Firm, Non-NOM Market Maker and/or Broker-Dealer* liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.20% to 0.30% of total industry customer equity and ETF option ADV contracts per day in a month would continue to receive a $0.42 per contract rebate.

Tier 4 currently offers Participants that add Customer and/or Professional liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.30% to 0.40% of total industry customer equity and ETF option ADV contracts per day in a month a $0.43 per contract rebate. The Exchange is proposing to amend Tier 4 to provide that Participants that add Customer, Professional, *Firm, Non-NOM Market Maker and/or Broker-Dealer* liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.30% to 0.40% of total industry customer equity and ETF option ADV contracts per day in a month would continue to receive a $0.43 per contract rebate.

Tier 5 currently offers Participants that add Customer and/or Professional liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.40% of total industry customer equity and ETF option ADV contracts per day in a month, or Participants that add (1) Customer and/or Professional liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of 25,000 or more contracts per day in a month, (2) the Participant has certified for the Investor Support Program set forth in Rule 7014, and (3) the Participant executed at least one order on NASDAQ's equity market a $0.45 per contract rebate. The Exchange is proposing to amend Tier 5 to provide that Participants that add Customer, Professional, *Firm, Non-NOM Market Maker and/or Broker-Dealer* liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.40% of total industry customer equity and ETF option ADV contracts per day in a month, or Participant adds (1) Customer and/or Professional liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of 25,000 or more contracts per day in a month, (2) the Participant has certified for the Investor Support Program set forth in Rule 7014, and (3) the Participant executed at least one order on NASDAQ's equity market would continue to receive a $0.45 per contract rebate.

Tier 8 currently offers Participants that add Customer and/or Professional liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of 0.75% or more of national customer volume in multiply-listed equity and ETF options classes in a month a $0.48 per contract Customer rebate and a $0.47 per contract Professional rebate. The Exchange is proposing to amend Tier 8 to provide that Participants that add Customer, Professional, *Firm, Non-NOM Market Maker and/or Broker-Dealer*

[7] Tiers 6 and 7 are calculated based on Total Volume. Total Volume is defined as Customer, Professional, Firm, Broker-Dealer, Non-NOM Market Maker and NOM Market Maker volume in Penny Pilot Options and/or Non-Penny Pilot Options which either adds or removes liquidity on NOM. *See* note ''b'' in Section 2, Chapter XV. The Exchange utilizes data from OCC to determine the total industry customer equity and ETF options ADV figure. OCC classifies equity and ETF options volume under the equity options category. Also, both customer and professional orders that are transacted on options exchanges clear in the customer range at OCC and therefore both customer and professional volume would be included in the total industry figure to calculate rebate tiers. This is the case today for the Total Volume number that appear in Tiers 6 and 7 of the Customer and Professional rebate today, which includes Customer and Professional numbers in both the numerator and denominator of that percentage. These tiers will remain unchanged by this proposal.

[8] The term ''Firm'' or (''F'') applies to any transaction that is identified by a Participant for clearing in the Firm range at OCC.

[9] The term ''Non-NOM Market Maker'' or (''O'') is a registered market maker on another options exchange that is not a NOM Market Maker. A Non-NOM Market Maker must append the proper Non-NOM Market Maker designation to orders routed to NOM

[10] The term ''Broker-Dealer'' or (''B'') applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category.

liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of 0.75% or more of national customer volume in multiply-listed equity and ETF options classes in a month would continue to receive a $0.48 per contract Customer rebate and a $0.47 per contract Professional rebate.

With respect to Tier 8, today, Participants that add Customer and/or Professional liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of 1.25% or more of national customer volume in multiply-listed equity and ETF options classes in a month will receive an additional $0.02 per contract Penny Pilot Options Tier 8 Customer Rebate to Add Liquidity for each transaction which adds liquidity in Penny Pilot Options in that month. The Exchange also proposes to amend this incentive by also permitting Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity to qualify for the incentive. The amended rule text would provide, ''Participants that add Customer, Professional, Firm, Non-NOM Market Maker, and/or Broker-Dealer liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of 1.25% or more of national customer volume in multiply-listed equity and ETF options classes in a month will receive an additional $0.02 per contract Penny Pilot Options Customer Rebate to Add Liquidity for each transaction which adds liquidity in Penny Pilot Options in that month.''

NOM Market Maker Rebates To Add Liquidity

Today, the Exchange pays NOM Market Maker Penny Pilot Options Rebates to Add Liquidity based on various criteria in six tiers with rebates which range from $0.20 to $0.42 per contract as noted below.

Monthly volume		Rebate to add liquidity
Tier 1	Participant adds NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of up to 0.10% of total industry customer equity and ETF option average daily volume (''ADV'') contracts per day in a month.	$0.20
Tier 2	Participant adds NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.10% to 0.25% of total industry customer equity and ETF option ADV contracts per day in a month.	$0.25
Tier 3	Participant adds NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.25% to 0.60% of total industry customer equity and ETF option ADV contracts per day in a month.	$0.30 or $0.40 in the following symbols QQQ, SPY and VXX.
Tier 4	Participant adds NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.60% to 0.90% of total industry customer equity and ETF option ADV contracts per day in a month.	$0.32 or $0.40 in the following symbols QQQ, VXX and SPY.
Tier 5	Participant adds NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.30% of total industry customer equity and ETF option ADV contracts per day in a month and qualifies for the Tier 7 or Tier 8 Customer and/or Professional Rebate to Add Liquidity in Penny Pilot Options.	$0.40
Tier 6	Participant adds NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.80% of total industry customer equity and ETF option ADV contracts per day in a month and qualifies for the Tier 7 or Tier 8 Customer and/or Professional Rebate to Add Liquidity in Penny Pilot Options or Participant adds NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.90% of total industry customer equity and ETF option ADV contracts per day in a month.	$0.42

Today, the Tier 3 NOM Market Maker Penny Pilot Options Rebate to Add Liquidity pays a $0.30 per contract rebate, except in QQQ, SPY and VXX which pay a $0.40 per contract rebate to Participants that add NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.25% to 0.60% of total industry customer equity and ETF option ADV contracts per day in a month. The Exchange proposes to add AAPL to the list of symbols that are eligible for the Tier 3 rebate of $0.40 per contract. Today, the Exchange pays a Tier 3 NOM Market Maker Penny Pilot Options Rebate to Add Liquidity of $0.30 per contract in AAPL. Today, the Tier 4 NOM Market Maker Penny Pilot Options Rebate to Add Liquidity pays a $0.32 per contract rebate, except in QQQ, SPY and VXX which pay a $0.40 per contract rebate to Participants that add NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of above 0.60% to 0.90% of total industry customer equity and ETF option ADV contracts per day in a month. The Exchange proposes to add AAPL to the list of symbols that are eligible for the Tier 4 rebate of $0.40 per contract. Today, the Exchange pays a Tier 4 NOM Market Maker Penny Pilot Options Rebate to Add Liquidity of $0.32 per contract in AAPL. The Exchange believes that paying a higher rebate for AAPL transactions will encourage a greater number of transactions in AAPL.

Today, the Tier 6 NOM Market Maker Penny Pilot Option Rebate to Add Liquidity pay a $0.42 per contract rebate to Participants that add NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.80% of total industry customer equity and ETF option ADV contracts per day in a month and qualifies for the Tier 7 or Tier 8 Customer and/or Professional Rebate to Add Liquidity in Penny Pilot Options or Participant adds NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.90% of total industry customer equity and ETF option ADV contracts per day in a month. The Exchange is proposing to amend the Tier 6 NOM Market Maker Penny Pilot Options Rebate to Add Liquidity to also provide that a Participant that adds Customer, Professional, Firm, Non-NOM Market Maker, and/or Broker-Dealer liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of 1.40% or more of national customer volume in multiply-listed equity and ETF options classes in a month may also qualify for the Tier 6 rebate of $0.42 per contract. This would provide Participants another method to qualify for the rebate.

2. Statutory Basis

NASDAQ believes that the proposed rule changes are consistent with the provisions of Section 6 of the Act,[11] in general, and with Section 6(b)(4) of the Act,[12] in particular, in that they provide

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(4).

for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which NASDAQ operates or controls as described in detail below.

Customer and Professional Rebates To Add Liquidity

The Exchange's proposal to amend the Customer and Professional Penny Pilot Options Rebates to Add Liquidity Tiers 1–5 and Tier 8 to provide that Participants may qualify for those rebates by adding not only Customer and Professional liquidity in Penny and/or Non-Penny Pilot Options, as specified in each tier, but also Firm, Non-NOM Market Maker and Broker-Dealer liquidity in Penny and/or Non-Penny Pilot Options is reasonable because the Exchange believes that the addition of the various types of market participant liquidity will allow additional Participants to qualify for these rebate tiers, who may not qualify today, or receive higher rebates. The Exchange believes that offering additional types of liquidity to qualify for the Customer and Professional Penny Pilot Options Rebates to Add Liquidity will incentivize Participants to send a greater amount of order flow to NOM.

The Exchange's proposal to amend the Customer and Professional Penny Pilot Options Rebates to Add Liquidity Tiers 1–5 and Tier 8 to provide that Participants may qualify for those rebates by adding not only Customer and Professional liquidity in Penny and/or Non-Penny Pilot Options, as specified in each tier, but also Firm, Non-NOM Market Maker and Broker-Dealer liquidity in Penny and/or Non-Penny Pilot Options is equitable and not unfairly discriminatory because the Exchange is permitting all types of market participant liquidity in Tiers 1–5 and Tier 8 of its Customer and Professional Penny Pilot Options rebate tiers as a means to qualify for these rebates. Further, all Participants may qualify to be eligible for these rebates, provided they transact the requisite amount of liquidity. Customer liquidity offers unique benefits to the market which benefits all market participants. Customer liquidity benefits all market participants by providing more trading opportunities, which attracts market makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. The Exchange believes that encouraging Participants to add Professional liquidity creates competition among options exchanges because the Exchange believes that the rebates may cause market participants to select NOM as a venue to send Professional order flow.

The Exchange believes that with respect to Tier 8, permitting Participants to add Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity, in addition to Customer and Professional liquidity, to qualify for the additional $0.02 per contract Tier 8 incentive is reasonable because the Exchange believes the opportunity to calculate the qualification for the incentive by adding other types of market participant liquidity will allow additional market participants to qualify for the incentive. Additionally, permitting other qualifying volume to count towards meeting the Tier 8 incentive will incentivize Participants to send a greater amount of order flow to NOM.

The Exchange believes that with respect to Tier 8, permitting Participants to add Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity, in addition to Customer and Professional liquidity, to qualify for the additional $0.02 per contract Tier 8 incentive is equitable and not unfairly discriminatory because all Participants are eligible for the Tier 8 incentive, provided they transact the requisite volume.

NOM Market Maker Penny Pilot Options Rebates To Add Liquidity

The Exchange's proposal to amend the NOM Market Maker Penny Pilot Options Rebate to Add Liquidity Tiers 3 and 4 to increase the AAPL rebate from $0.30 to $0.40 per contract in Tier 3 and from $0.32 to $0.40 per contract in Tier 4 is reasonable because the proposal seeks to encourage Participants to transact a greater amount of AAPL liquidity in order to receive the higher rebate of $0.40 per contract. The Exchange believes that offering Participants NOM Market Makers the ability to obtain higher rebates is reasonable because it will encourage additional order interaction.

The Exchange's proposal to amend the NOM Market Maker Penny Pilot Options Rebate to Add Liquidity Tiers 3 and 4 to increase the AAPL rebate from $0.30 to $0.40 per contract in Tier 3 and from $0.32 to $0.40 per contract in Tier 4 is equitable and not unfairly discriminatory because all NOM Market Makers may qualify for the Tier 3 and Tier 4 NOM Market Maker Penny Pilot Options Rebate to Add Liquidity.

The Exchange believes that it is reasonable, equitable, and not unfairly discriminatory to adopt different pricing for AAPL, as compared to other options, because pricing by symbol is a common practice on many U.S. options exchanges as a means to incentivize order flow to be sent to an exchange for execution in the most actively traded options classes, in this case actively traded Penny Pilot Options.[13] The Exchange notes that AAPL is one of the most actively traded options in the U.S. The Exchange believes that this pricing will incentivize members to transact options on AAPL on NOM in order to obtain the higher $0.40 per contract rebate.

The Exchange's proposal to amend the Tier 6 NOM Market Maker Penny Pilot Options Rebate to Add Liquidity to offer an additional method[14] to qualify for the $0.42 per contract rebate is reasonable because additional Participants may qualify for the Tier 6 rebate if they are able to transact the requisite volume specified in the additional proposed qualification to add any type of market participant liquidity. The Exchange also believes that this amendment to the Tier 6 NOM Market Maker Penny Pilot Options Rebate to Add Liquidity will incentivize Participants to send a greater amount of order flow to NOM.

The Exchange's proposal to amend the Tier 6 NOM Market Maker Penny Pilot Options Rebate to Add Liquidity to offer an additional method to qualify for the $0.42 per contract is equitable and not unfairly discriminatory because all Participants may qualify for the Tier 6 rebate provided they transact the requisite amount of liquidity.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASDAQ does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

[13] *See* NASDAQ OMX PHLX LLC's Pricing Schedule. *See also* the International Securities Exchange LLC's Fee Schedule. Both of these markets segment pricing by symbol.

[14] Today, a Participant may qualify for the NOM Market Maker Tier 6 Rebate to Add Liquidity in Penny Pilot Options by adding NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.80% of total industry customer equity and ETF option ADV contracts per day in a month and qualifying for the Tier 7 or Tier 8 Customer and/or Professional Rebate to Add Liquidity in Penny Pilot Options or adding NOM Market Maker liquidity in Penny Pilot Options and/or Non-Penny Pilot Options above 0.90% of total industry customer equity and ETF option ADV contracts per day in a month. The Exchange is amending Tier 6 to permit a Participant to qualify for the $0.42 per contract rebate by adding Customer, Professional, Firm, Non-NOM Market Maker, and/or Broker-Dealer liquidity in Penny Pilot Options and/or Non- Penny Pilot Options of 1.40% or more of national customer volume in multiply-listed equity and ETF options classes in a month

The Exchange believes that amending Tiers 1–5 and Tier 8 of the Customer and Professional Penny Pilot Options Rebates to Add Liquidity, as well as the Tier 8 incentive of $0.02 per contract to permit Participants to add all types of market participant liquidity does not create an undue burden on competition, rather the proposal will incentivize market participants to send additional order flow to the Exchange. Customer liquidity offers unique benefits to the market which benefits all market participants. Customer liquidity benefits all market participants by providing more trading opportunities, which attracts market makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. The Exchange believes that encouraging Participants to add Professional liquidity creates competition among options exchanges because the Exchange believes that the rebates may cause market participants to select NOM as a venue to send Professional order flow.

The Exchange's proposal to amend the Tier 3 and 4 NOM Market Maker Penny Pilot Options Rebates to Add Liquidity to pay a higher rebate for AAPL of $0.40 per contract, similar to SPY, QQQ and VXX, does not create an undue burden on competition because all NOM Market Makers may qualify for the Tier 3 or 4 NOM Market Maker Penny Pilot Options Rebate to Add Liquidity. The Exchange's proposal to offer another means to qualify for the Tier 6 NOM Market Maker Penny Pilot Options Rebate to Add Liquidity does not create an undue burden on competition, rather the proposal will incentivize market participants to send additional order flow to the Exchange.

The Exchange believes the differing outcomes, rebates and fees created by the Exchange's proposed pricing incentives contribute to the overall health of the market place to the benefit of all Participants that willing choose to transact options on NOM. For the reasons specified herein, the Exchange does not believe this proposal creates an undue burden on competition. The Exchange operates in a highly competitive market comprised of twelve U.S. options exchanges in which many sophisticated and knowledgeable market participants can readily and do send order flow to competing exchanges if they deem fee levels or rebate incentives at a particular exchange to be excessive or inadequate. These market forces support the Exchange belief that the proposed rebate structure and tiers proposed herein are competitive with rebates and tiers in place on other exchanges. The Exchange believes that this competitive marketplace continues to impact the rebates present on the Exchange today and substantially influences the proposals set forth above.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[15] 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. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or 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–NASDAQ–2014–105 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2014–105. 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–NASDAQ–2014–105, and should be submitted on or before December 22, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–28172 Filed 11–28–14; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73677; File No. SR–BATS–2014–058]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Rule 11.24 of BATS Exchange, Inc.

November 24, 2014.

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 November 17, 2014, BATS Exchange, Inc. (the ''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A) of the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Act [3] and Rule 19b–4(f)(6) thereunder,[4] which renders it effective upon filing with the Commission. 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 the Substance of the Proposed Rule Change

The Exchange filed a proposal to re-number Rule 11.24, entitled ''Retail Order Attribution Program,'' as Rule 11.25.

The text of the proposed rule change is available at the Exchange's Web site at *http://www.batstrading.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts 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 is proposing to re-number Rule 11.24, entitled ''Retail Order Attribution Program,'' as Rule 11.25. The Exchange recently adopted this rule to allow retail orders to be attributed as such on Exchange data feeds.[5] However, at the time such proposal was filed, the Exchange was awaiting approval of a separate filing to add an opening process for non-Exchange-listed securities, which rule was also numbered 11.24. Accordingly, the Exchange proposes to re-number the rule related to its Retail Order Attribution Program as 11.25.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act'') [6] and further the objectives of Section 6(b)(5) of the Act [7] because it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and, in general, to protect investors and the public interest. Specifically, the correction of this numbering error will contribute to the protection of investors and the public interest by helping to avoid confusion with respect to Exchange rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition as it is not a competitive proposal and does not reflect any substantive modification to the Exchange's operations.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Not applicable.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [8] and Rule 19b–4(f)(6) thereunder.[9] 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 Act and Rule 19b–4(f)(6) thereunder.[10]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [11] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [12] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it would allow the Exchange to immediately correct the numbering error described above. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[13]

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. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or 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–BATS–2014–058 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BATS–2014–058. 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/*

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Securities Exchange Act Release No. 73237 (September 26, 2014), 79 FR 59537 (October 2, 2014) (SR–BATS–2014–043).

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6).

[10] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change.

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6)(iii).

[13] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–BATS–2014–058, and should be submitted on or before December 22, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–28173 Filed 11–28–14; 8:45 am]

BILLING CODE 8011–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Membership of the Performance Review Board (PRB)

AGENCY: Office of the United States Trade Representative.

ACTION: Notice

SUMMARY: The following staff members have been appointed to serve on the Performance Review Board:
Performance Review Board (PRB)
Chair: Wendy Cutler
Member: Barbara Weisel
Member: Florizelle Liser
Member: Lewis Karesh
Member: Sharon Bomer-Lauritsen
Executive Secretary: Ronald Nerida

DATES: *Effective Date:* November 20, 2014

FOR FURTHER INFORMATION CONTACT: Questions regarding this submission should be directed to Susan Buck, Acting Director, USTR Office of Human Resources (202) 395–7630.

Fred Ames,

Assistant U.S. Trade Representative for Administration, Office of the United States Trade Representative.

[FR Doc. 2014–28179 Filed 11–28–14; 8:45 am]

BILLING CODE 3290–F4–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Safety Advisory 2014–02]

Roadway Worker Authority Limits—Importance of Clear Communication, Compliance with Applicable Rules and Procedures, and Ensuring that Appropriate Safety Redundancies Are in Place in the Event of Miscommunication or Error; Correction

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of Safety Advisory; Correction

SUMMARY: On November 25, 2014, FRA published a document in the **Federal Register** to reemphasize the importance of clear communication and compliance with applicable rules and procedures regarding roadway worker authority limits on controlled track, and to ensure that appropriate safety redundancies are in place to protect against miscommunication or error. The document contained an incorrect job designation (''foreman'' instead of ''roadway worker in charge'') for an employee in the first incident discussed in the safety advisory that resulted in an employee fatality, and an incorrect location (''Danbury,'' instead of ''West Haven,'' Connecticut) for the second incident that also resulted in an employee fatality. The safety advisory otherwise remains unchanged.

FOR FURTHER INFORMATION CONTACT: Kenneth Rusk, Staff Director, Track Division, Office of Railroad Safety, FRA, 1200 New Jersey Avenue SE., Washington, DC 20590, telephone (202) 493–6236; or Anna Nassif Winkle, Trial Attorney, Office of Chief Counsel, FRA, 1200 New Jersey Avenue SE., Washington, DC 20590, telephone (202) 493–6166.

Correction

In the **Federal Register** of November 25, 2014, in FR Doc. 2014–27955, on page 70268, in the third column, correct the second and third paragraphs to read as follows:

In November 2013, a BNSF Railway Co. (BNSF) lead welder was killed when his welding truck collided with an eastbound freight train on a single main track at a location that was outside of his roadway work group's limits of authority. It appears from FRA's preliminary investigation that the two-man work group set on the track at a location outside of their authority limits after the workers disagreed regarding the extent of the authority limits and after not being able to quickly resolve the discrepancy because the screen displaying their authority was not visible at the time they set on the track. The roadway worker in charge was apparently attempting to ''wake up'' the computer screen as the operator was setting their vehicle on and operating over the track, rather than remaining clear of the track until the discrepancy could be resolved, as required by the railroad's good faith challenge procedures.

In May 2013, a Metro-North Commuter Railroad Co. (Metro-North) track foreman was struck and killed by a passenger train in West Haven, Connecticut, after a student dispatcher prematurely removed the control signal blocking devices that had been established for the track foreman's work group, and cleared the signal for the passenger train. Investigation by FRA and the National Transportation Safety Board (NTSB) determined that the student dispatcher assumed that the foreman no longer needed the main track after the dispatcher had lined the foreman-piloted locomotive crane into an out-of-service track. Several weeks prior to this incident, a very similar incident occurred on the same railroad. However, in that situation, the roadway worker detected the advancing train movement in sufficient time to move away from the track and avoid being struck by the train.

Dated: November 26, 2014.

Brenda Moscoso,

Director, Office of Safety Analysis.

[FR Doc. 2014–28380 Filed 11–28–14; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

November 25, 2014.

The Department of the Treasury is planning to 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.

DATES: Comments should be received on or before January 30, 2015 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 Kim M. Bloomquist, Internal Revenue

[14] 17 CFR 200.30–3(a)(12).

Service, Office of Research, Compliance Analysis and Modeling (RAS:R:CAM), 1111 Constitution Ave. NW., K–3rd Floor/006, Washington, DC 20224, Email: *kim.bloomquist@irs.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.*

Internal Revenue Service

OMB Number: 1545–XXXX.

Type of Review: New Collection.

Title: Pilot Test of Consumer Tipping Survey.

Abstract: The IRS is charged with collecting revenue legally owed to the federal government. One important category of income comes in the form of tips. Previous empirical research has shown income from tips to be significantly underreported, limiting the IRS's ability to collect the proper amount of tax revenue. The IRS believes a new study of consumer tipping practices is needed in order to better understand current tip reporting behavior so tax administrators and policy makers can make the tax system fairer and more efficient. Therefore, the IRS wishes to develop updated estimates of consumer tipping revenue across numerous services where tipping is prevalent.

In support of this mission, IRS is seeking a standard clearance to conduct a one-month pilot test in preparation for a nation-wide consumer tipping survey. There exists a substantial difference in the cost per response between a probability and non-probability sample. Pilot tests are therefore necessary to determine the relative accuracy and selection bias of tipping data that are collected using these different sampling methodologies in order to determine if there is tradeoff between accuracy and cost. The results of the pilot will be used to determine the sampling method employed in a nation-wide survey.

Affected Public: Individuals.

Estimated Total Annual Burden Hours: 4,717.

Robert Dahl,

Treasury PRA Clearance Officer.

[FR Doc. 2014–28214 Filed 11–28–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Publication of the Tier 2 Tax Rates

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: Publication of the tier 2 tax rates for calendar year 2015 as required by section 3241(d) of the Internal Revenue Code (26 U.S.C. 3241). Tier 2 taxes on railroad employees, employers, and employee representatives are one source of funding for benefits under the Railroad Retirement Act.

DATES: The tier 2 tax rates for calendar year 2015 apply to compensation paid in calendar year 2015.

FOR FURTHER INFORMATION CONTACT: Kathleen Edmondson, CC:TEGE:EOEG:ET1, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224, Telephone Number (202) 317–6798 (not a toll-free number). TIER 2 TAX RATES: The tier 2 tax rate for 2015 under section 3201(b) on employees is 4.9 percent of compensation. The tier 2 tax rate for 2015 under section 3221(b) on employers is 13.1 percent of compensation. The tier 2 tax rate for 2015 under section 3211(b) on employee representatives is 13.1 percent of compensation.

Dated: November 21, 2014.

Victoria A. Judson,

Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities).

[FR Doc. 2014–28176 Filed 11–28–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Loan Guaranty: Assistance to Eligible Individuals in Acquiring Specially Adapted Housing; Cost-of-Construction Index

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The U.S. Department of Veterans Affairs (VA) announces that the aggregate amounts of assistance available under the Specially Adapted Housing (SAH) grant program will increase by 4.307 percent for Fiscal Year (FY) 2015.

DATES: December 1, 2014

FOR FURTHER INFORMATION CONTACT: John Bell, III, Assistant Director for Loan Policy and Valuation, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 632–8786 (not a toll-free number).

SUPPLEMENTARY INFORMATION: In accordance with 38 U.S.C. 2102(e) and 2102A(b)(2) and 38 CFR 36.4411, the Secretary of Veterans Affairs announces for FY 2015 the aggregate amounts of assistance available to veterans and servicemembers eligible for SAH program grants.

Public Law 110–289, the Housing and Economic Recovery Act of 2008, authorized the Secretary to increase the aggregate amounts of SAH assistance annually based on a residential home cost-of-construction index. The Secretary uses the Turner Building Cost Index for this purpose.

In the most recent quarter for which the Turner Building Cost Index is available, Quarter 2 FY 2014, the index showed an increase of 4.307 percent over the index value in Quarter 2 FY 2013. Pursuant to 38 CFR 36.4411(a), therefore, the aggregate amounts of assistance for SAH grants made pursuant to 38 U.S.C. 2101(a) or 2101(b) will increase by 4.307 percent for FY 2015.

Public Law 112–154, the Honoring America's Veterans and Caring for Camp Lejeune Families Act of 2012, required that the same percentage of increase apply to grants authorized pursuant to 38 U.S.C. 2102A. See 38 U.S.C. 2102A(b)(2). As such, the maximum amount of assistance available under these grants, which are called grants for Temporary Residence Adaptation (TRA grants), will also increase by 4.307 percent for FY 2015.

The increases are effective as of October 1, 2014.

Specially Adapted Housing: Aggregate Amounts of Assistance Available During Fiscal Year 2015

2101(a) Grants and TRA Grants

Effective October 1, 2014, the aggregate amount of assistance available for SAH grants made pursuant to 38 U.S.C. 2101(a) will be $70,465 during FY 2015. The maximum TRA grant made to an individual who satisfies the eligibility criteria under 38 U.S.C. 2101(a) and 2102A will be $30,934 during FY 2015.

2101(b) Grants and TRA Grants

Effective as of October 1, 2014, the aggregate amount of assistance available for SAH grants made pursuant to 38 U.S.C. 2101(b) will be $14,093 during FY 2015. The maximum TRA grant made to an individual who satisfies the eligibility criteria under 38 U.S.C. 2101(b) and 2102A will be $5,523 during FY 2015.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of

the Department of Veterans Affairs. Jose D. Riojas, Chief of Staff, Department of Veterans Affairs, approved this document on November 4, 2014, for publication.

Dated: November 25, 2014.

William F. Russo,

Acting Director, Office of Regulation Policy & Management, Office of the General Counsel, Department of Veterans Affairs.

[FR Doc. 2014–28228 Filed 11–28–14; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 79 Monday,

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 11 and 101

Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Calorie Labeling of Articles of Food in Vending Machines; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

[Docket No. FDA–2011–F–0172]

RIN 0910–AG57

Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: To implement the nutrition labeling provisions of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act or ACA), the Food and Drug Administration (FDA or we) is requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. The ACA, in part, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act), among other things, to require restaurants and similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items to provide calorie and other nutrition information for standard menu items, including food on display and self-service food. Under provisions of the ACA, restaurants and similar retail food establishments not otherwise covered by the law may elect to become subject to these Federal requirements by registering every other year with FDA. Providing accurate, clear, and consistent nutrition information, including the calorie content of foods, in restaurants and similar retail food establishments will make such nutrition information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices.

DATES: *Effective date:* December 1, 2015.

Compliance date: Covered establishments must comply with the rule by December 1, 2015. See section XXIII for more information on the effective and compliance dates.

Comment Date: Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by December 31, 2014 (see section XXVI, the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: To ensure that comments on the information collection are received, the Office of Management and Budget (OMB) recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910-New and title ''Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Y. Reese, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371, email: *Daniel.Reese@fda.hhs.gov.*

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Executive Summary

Purpose and Coverage of the Final Rule

More than two thirds of adults and about a third of children in the United States are overweight or obese. Overconsumption of calories is one of the primary risk factors for overweight and obesity. About half of consumers' annual food dollars are spent on, and a third of total calories come from, foods prepared outside the home, including foods from restaurants and similar retail food establishments. Many people do not know, or underestimate, the calorie and nutrient content of these foods. To help make nutrition information for these foods available to consumers in a direct, accessible, and consistent manner to enable consumers to make informed and healthful dietary choices, section 4205 of the ACA requires that calorie and other nutrition information be provided to consumers in restaurants and similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items (chain retail food establishment). Section 4205 of the ACA also provides that a restaurant or similar retail food establishment that is not a chain retail food establishment may elect to be subject to section 4205's nutrition labeling requirements by registering every other year with FDA.

To be covered by this rule, an establishment must satisfy several criteria. First, the establishment must be a restaurant or similar retail food establishment. Under this rule, that means a retail establishment that offers for sale restaurant-type food, except if it is a school as defined in 7 CFR 210.2 or 220.2. Restaurants and similar retail food establishments include bakeries, cafeterias, coffee shops, convenience stores, delicatessens, food service facilities located within entertainment venues (such as amusement parks, bowling alleys, and movie theatres), food service vendors (*e.g.,* ice cream shops and mall cookie counters), food take-out and/or delivery establishments (such as pizza take-out and delivery establishments), grocery stores, retail confectionary stores, superstores, quick service restaurants, and table service restaurants.

The rule defines ''restaurant-type food'' in a way that both focuses on the food most like the food offered for sale in restaurants and reflects the statutory context of section 4205 of the ACA. The table that follows provides examples of foods that generally would be considered restaurant-type food (*e.g.,* foods that are usually eaten on the premises, while walking away, or soon after arriving at another location), as well as examples of foods that generally would be not be considered restaurant-type food (*e.g.,* foods that are grocery-type items that consumers often store for use at a later time or customarily further prepare), for the purposes of this rule.

EXAMPLES OF FOODS THAT GENERALLY WOULD OR WOULD NOT BE CONSIDERED RESTAURANT-TYPE FOOD

Examples of foods that generally would be considered restaurant-type food	Examples of foods that generally would not be considered restaurant-type food
• Food for immediate consumption at a sit-down or quick service restaurant. • Food purchased at a drive-through establishment ..... • Food purchased at a drive-through establishment ..... • Take-out and delivery pizza; hot pizza at grocery and convenience stores that is ready to eat; pizza slice from a movie theater. • Hot buffet food, hot soup at a soup bar, and food from a salad bar ... • Foods ordered from a menu/menu board at a grocery store intended for individual consumption (e.g., soups, sandwiches, and salads). • Self-service foods and foods on display that are intended for individual consumption (e.g., sandwiches, wraps, and paninis at a deli counter; salads plated by the consumer at a salad bar; cookies from a mall cookie counter; bagels, donuts, rolls offered for individual sale).	• Certain foods bought from bulk bins or cases (e.g., dried fruit, nuts) in grocery stores • Foods to be eaten over several eating occasions or stored for later use (e.g., loaves of bread, bags or boxes of dinner rolls, whole cakes, and bags or boxes of candy or cookies) • Foods that are usually further prepared before consuming (e.g., deli meats and cheeses) • Foods sold by weight that are not self-serve and are not intended solely for individual consumption (e.g., deli salads sold by unit of weight such as potato salad, chicken salad), either prepacked or packed upon consumer request

Consistent with the statute, to be covered by the rule, a restaurant or similar retail establishment must be ''part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items.'' A restaurant or similar retail food establishment that does not satisfy these criteria may choose to be covered by the rule by registering with FDA using a process established in the rule.

Under the rule, ''location'' means a fixed position or site. Transportation venues such as trains and airplanes are not covered by the rule because they do not have a fixed position or site. ''Doing business under the same name'' means a restaurant or similar retail food establishment must share the same name as other establishments in the chain (regardless of the type of ownership of the locations, *e.g.,* individual franchises). The term ''name'' refers to either the name of the establishment presented to the public or, if there is no name of the establishment presented to the public (*e.g.,* an establishment with the generic descriptor ''concession stand''), the name of the parent entity of the establishment. ''Offering for sale substantially the same menu items'' means offering for sale a significant proportion of menu items that use the same general recipe and are prepared in substantially the same way with substantially the same food components, even if the name of the menu item varies.

The nutrition labeling requirements of the rule apply to standard menu items offered for sale in covered establishments. ''Standard menu item'' means a restaurant-type food that is routinely included on a menu or menu board or routinely offered as a self-service food or food on display. The nutrition labeling requirements are not applicable to certain foods, including foods that are not standard menu items, such as condiments, daily specials, temporary menu items, custom orders, and food that is part of a customary market test; and self-service food and food on display that is offered for sale for less than a total of 60 days per calendar year or fewer than 90 consecutive days in order to test consumer acceptance. In addition, the rule exempts alcohol beverages that are food on display and are not self-service food (*e.g.,* bottles of liquor behind the bar used to prepare mixed drinks) from the labeling requirements that apply to food on display.

Summary of the Major Provisions of the Final Rule

The rule includes provisions that:

- Define terms, including terms that describe criteria for determining whether an establishment is subject to the rule;
- Establish which foods are subject to the nutrition labeling requirements and which foods are not subject to these requirements;
- Require that calories for standard menu items be declared on menus and menu boards that list such foods for sale;
- Require that calories for standard menu items that are self-service or on display be declared on signs adjacent to such foods;
- Require that written nutrition information for standard menu items be available to consumers who ask to see it;
- Require, on menus and menu boards, a succinct statement concerning suggested daily caloric intake (succinct statement), designed to help the public understand the significance of the calorie declarations;
- Require, on menus and menu boards, a statement regarding the availability of the written nutrition information (statement of availability);
- Establish requirements for determination of nutrient content of standard menu items;
- Establish requirements for substantiation of nutrient content determined for standard menu items, including requirements for records that a covered establishment must make available to FDA within a reasonable period of time upon request; and
- Establish terms and conditions under which restaurants and similar retail food establishments not otherwise subject to the rule could elect to be subject to the requirements by registering with FDA.

Costs and Benefits

The statute requires nutrition labeling for standard menu items on menus and menu boards for certain restaurants and similar retail food establishments and calorie labeling for food sold from certain vending machines. FDA is issuing two separate final rules (one for menu labeling and one for vending machine labeling) to implement those labeling requirements. Taken together the labeling requirements (of the menu labeling and vending machine labeling rules combined) are estimated to have benefits exceeding costs by $477.9 million on an annualized basis (over 20 years discounted at 7 percent).

SUMMARY OF COSTS AND BENEFITS OF MENU LABELING AND VENDING MACHINE RULES

[In millions]

	Rate	Potential benefits	Estimated costs	Net benefits
Total for Labeling (menu and vending rules) over 20 years*	3	$9,221.3	$1,697.9	$7,523.4
	7	6,752.8	1,333.9	5,418.9
Annualized for Labeling (menu and vending rules) over 20 years*	3	601.9	110.8	491.1
	7	595.5	117.6	477.9
Total for Menu Labeling over 20 years	3	9,221.3	1,166.8	8,054.5
	7	6,752.8	932.8	5,820.0
Annualized for Menu Labeling over 20 years	3	601.9	76.9	525.01
	7	595.5	84.5	510.99

*Benefits for the vending machine labeling rule are not quantified and are not counted in these values.

I. Background

More than two thirds of adults and about a third of children in the United States are overweight or obese (Refs. 1 and 2). Overconsumption of calories is one of the primary risk factors for overweight and obesity (Ref. 3). About half of consumers' annual food dollars are spent on, and a third of total calories come from, foods prepared outside the home, including foods from restaurants and similar retail food establishments (Refs. 4 to 6). Research indicates that many people do not know, or underestimate, the calorie and nutrient content of these foods (Ref. 7).

Since the early 1990s, the Nutrition Labeling and Education Act of 1990 (NLEA) and our regulations in § 101.9 (21 CFR 101.9) implementing the NLEA have required that the labeling for many foods bear nutrition information, including calorie information. However, as we noted in the proposed rule (76 FR 19192 at 19193; April 6, 2011), the NLEA left a gap in the Federal requirements for nutrition labeling through certain exemptions. The NLEA included an exemption for nutrition labeling for food that is ''served in restaurants or other establishments in which food is served for immediate human consumption'' or ''sold for sale or use in such establishments'' (section 403(q)(5)(A)(i) of the FD&C Act) (21 U.S.C. 343(q)(5)(A)(i)). The NLEA also included an exemption for food of the type described in section 403(q)(5)(A)(i) that is primarily processed and prepared in a retail establishment, ready for human consumption, ''offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment'' (section 403(q)(5)(A)(ii) of the FD&C Act). However, these exemptions were contingent on there being no nutrient content claims or health claims made on the label or labeling, or in the advertising, for the food. Current provisions in § 101.10 (21 CFR 101.10) require restaurants and other establishments in which food is offered for human consumption that make either a nutrient content claim (defined in § 101.13 (21 CFR 101.13)) or health claim (defined in 21 CFR 101.14) to provide certain nutrition information upon request. For example, if a menu lists an entree as being low in fat, information about the amount of fat in the entree must be available upon request (§ 101.10).

Section 101.9(j)(2) of our regulations implementing the NLEA includes examples of restaurants or other establishments in which food sold for immediate human consumption generally was exempted from nutrition labeling requirements under the NLEA. Section 101.9(j)(3) of these regulations includes examples of food sold in establishments in which food is processed and prepared, ready for human consumption, offered for sale to consumers but not for immediate consumption, and not offered for sale outside of the establishments.

Several State and local governments enacted their own laws requiring nutrition labeling on menus and menu boards to fill the gap in the Federal requirements. However, these State and local requirements vary significantly in their substantive requirements and the set of establishments to which they apply.

On March 23, 2010, the ACA (Pub. L. 111–148) was signed into law. Section 4205 of the ACA amends section 403(q) of the FD&C Act, which governs nutrition labeling requirements, and section 403A of the FD&C Act (21 U.S.C. 343–1), which governs Federal preemption of State and local food labeling requirements. As amended, section 403(q)(5)(H) of the FD&C Act requires chain retail food establishments with 20 or more locations to provide calorie information for standard menu items, including food on display and self-service food, and to provide, upon consumer request, additional written nutrition information for standard menu items (21 U.S.C. 343(q)(5)(H)(i) to (iii)). Section 403(q)(5)(H) of the FD&C Act also provides that a restaurant or similar retail food establishment not otherwise subject to the requirements of section 403(q)(5)(H) (*e.g.,* a restaurant that is not part of a chain with 20 or more locations) may elect to be subject to the requirements of section 403(q)(5)(H) by registering every other year with FDA (21 U.S.C. 343(q)(5)(H)(ix)). Thus, ''covered establishments'' include both chain retail food establishments and other restaurants or similar retail food establishments that voluntarily register to be subject to the rule. A standard menu item offered for sale in a covered establishment is deemed to be misbranded if the requirements of section 403(q)(5)(H) are not met.

Section 4205 of the ACA became effective on the date the law was signed, March 23, 2010; however, FDA must issue rules before some provisions can be required. On July 7, 2010, we published a notice in the **Federal Register** to solicit comments and suggestions on the new law (2010 docket notice) (75 FR 39026). On August 25, 2010, we published for public comment a draft guidance entitled ''Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010'' (draft implementation guidance) (Ref. 8) (75 FR 52426), describing which provisions became requirements upon enactment of the law, which provisions we would implement through rulemaking, and draft interpretations of certain provisions, including a broad interpretation of the scope of establishments covered. On January 25, 2011, we published in the **Federal Register** a notice withdrawing the draft implementation guidance (76 FR 4360) and announcing our intent to exercise our enforcement discretion until we

complete the notice and comment rulemaking process.

In the **Federal Register** of April 6, 2011 (76 FR 19192), we issued a proposed rule (proposed rule) to implement the requirements of section 4205 of the ACA for the nutrition labeling of standard menu items in certain restaurants and similar retail food establishments. We requested public comments on the proposed requirements and some alternatives by June 6, 2011. In the **Federal Register** of May 24, 2011 (76 FR 30050), we issued a document (correction document) correcting errors in the proposed rule, including errors in cross-references, an incomplete address, and a typographical error in the codified section of the document. In the **Federal Register** of May 24, 2011 (76 FR 30051), we extended the comment period until July 5, 2011.

In the proposed rule, we described both the provisions that became requirements upon enactment (*i.e.,* they are self-executing) and the provisions that depend on FDA to issue rules before they can become effective (76 FR 19192 at 19194). We also noted that we had published the draft implementation guidance and described the issues addressed by the draft implementation guidance. In the proposed rule, we reiterated that we intended to exercise enforcement discretion for the self-executing provisions of section 4205 of the ACA and described our reasons for doing so (76 FR 19192 at 19194).

After considering comments to the proposed rule, we are issuing this final rule to implement the requirements of section 4205 of the ACA for the nutrition labeling of standard menu items in certain chain restaurants and similar retail food establishments.

In addition to the nutrition labeling requirements for standard menu items, other amendments made by section 4205 of the ACA to the FD&C Act (specifically, section 403(q)(5)(H)(viii)(I)) establish calorie disclosure requirements for certain articles of food sold from vending machines. We published a proposed rule to implement the vending machine provisions of section 403(q) of the FD&C Act on April 6, 2011 (76 FR 19238; the proposed vending machine rule). Elsewhere in this issue of the **Federal Register**, we are issuing a final rule to implement the vending machine provisions of section 403(q)(5)(H)(viii)(I) of the FD&C Act.

II. Legal Authority

On March 23, 2010, the ACA was signed into law. Section 4205 of the ACA amended section 403(q)(5) of the FD&C Act by amending section 403(q)(5)(A) and by creating new clause (H), which requires, in relevant part, covered establishments to provide certain nutrient declarations for standard menu items in the labeling for such foods. Under section 403(f) of the FD&C Act, any word, statement, or other information required by or under authority of the FD&C Act to appear on the label or labeling of a food is required to be prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Under section 403(a)(1) of the FD&C Act, food labeling must be truthful and non-misleading. Because food that is not in compliance with section 403 is deemed misbranded, food to which these requirements apply is deemed misbranded if these requirements are not met. In addition, under section 201(n) of the FD&C Act (21 U.S.C. 321(n)), the labeling of a food is misleading if it fails to reveal facts that are material in light of representations made in the labeling or with respect to consequences that may result from use. Section 403(q)(5)(H)(x) of the FD&C Act requires that the Secretary of Health and Human Services (Secretary) issue regulations to carry out requirements in section 403(q)(5)(H). Section 701(a) of the FD&C Act (21 U.S.C. 371(a)) vests the Secretary with the authority to issue regulations for the efficient enforcement of the FD&C Act. Thus, we have the authority to issue this final rule under sections 201(n), 403(a)(1), 403(f), 403(q)(5)(H), and 701(a) of the FD&C Act.

We have revised our labeling regulations by adding new § 101.11 to require that covered establishments provide calorie and other nutrition information for standard menu items, including food on display and self-service food. Also, we are establishing the terms and conditions for voluntary registration by establishments that are not otherwise subject to the requirements of section 4205 of the ACA but elect to become subject to such requirements.

III. General Comments on the Proposed Rule

A. Introduction

We received approximately 900 submissions on the proposed rule by the close of the comment period, each containing one or more comments. We received submissions from consumers; consumer groups; trade organizations; industry (including restaurants, entertainment venues, food service operations, and grocery stores); public health organizations; public advocacy groups; contractors; Congress; Federal, State, and local Government Agencies; and other organizations.

We describe and respond to the comments in sections III, IV, VI through XXIV, and XXVII of this document. To make it easier to identify comments and our responses, the word ''Comment,'' in parentheses, appears before the comment's description, and the word ''Response,'' in parentheses, appears before our response. We have also numbered each comment and response to help distinguish between different comments and responses. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was received.

B. Description of General Comments and FDA Response

Many comments made general remarks supporting or opposing the rule and did not focus on a particular section of the rule. The majority of these comments expressed general support for nutrition labeling of standard menu items in covered establishments, and we do not discuss them in detail. In the following paragraphs, we discuss general comments that did not support the rule as proposed.

(Comment 1) Some comments stated that people do not need to be told what to eat. Some comments asserted that calorie disclosure on menus will either cause eating disorders or affect those with eating disorders. Other comments asserted that the menu labeling requirements will not affect consumer behavior, there will be information overload, and people will ignore the information. Some comments considered that the menu labeling requirements will promote healthier choices, whereas other comments considered that the menu labeling requirements will not promote healthier choices. Some comments supported the menu labeling requirements but considered that education is needed to fight obesity.

(Response 1) The rule does not tell consumers what they should or should not eat. The nutrition labeling required by section 4205 of the ACA will provide nutrition information to consumers in covered establishments in a direct, accessible, and consistent manner to enable consumers to make informed choices about the foods they purchase in such establishments.

About half of consumers' annual food dollars are spent on, and a third of total calories come from, foods prepared outside of the home, including foods from restaurants or similar retail food establishments (Refs. 4 to 6). Further, research indicates that many people do not know, or underestimate, the calorie and nutrient content of these foods (Ref. 7). Accordingly, providing direct access to nutrition information for these foods will enable consumers to make informed decisions within the context of nutrition regarding the foods they purchase in restaurants or similar retail food establishments. Providing nutrition information to consumers for standard menu items offered for sale in covered establishments will give consumers much needed access to essential nutrition information for a large and growing number of the foods they purchase and consume. In addition, it will allow consumers to make informed nutritional comparisons between different foods and informed purchase decisions. Further, section 4205 of the ACA and this rule require covered establishments to post, on menus and menu boards, a succinct statement concerning suggested daily caloric intake designed to enable consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards. This statement, along with the required calorie information, will enable consumers to better understand the significance of the calorie information provided on menus and menu boards and the potential impacts of overconsumption of calories. As a result, the information will enable consumers to assess their calorie intake during short- or long-term settings and better understand how the foods that they purchase at covered establishments fit within their daily caloric and other nutritional needs.

The comments provided no evidence that the provision of nutrition labeling at the point of purchase causes or adversely affects those with eating disorders. For nearly two decades, consumers have had access to this type of information on the labels of packaged foods that bear the Nutrition Facts label in accordance with § 101.9. We are not aware of data or other information demonstrating that the availability of nutrition information through the Nutrition Facts Panel has either caused eating disorders or negatively impacted persons with eating disorders. In addition, Congress, through section 4205 of the ACA, requires covered establishments to provide calorie and other nutrition information for standard menu items. This rulemaking implements that Congressional mandate.

(Comment 2) Some comments considered that the requirements are unnecessary because most ''fast food'' restaurants have the information already. One comment considered that the proposed requirements constitute a tax increase designed to relieve the individual of personal responsibility.

(Response 2) Section 4205 of the ACA requires covered establishments to provide calorie and other information for standard menu items on menus, menu boards, signs adjacent to self-service foods and foods on display and additional nutrition information for standard menu items in written form, available on the premises, to consumers on request. Therefore, section 4205 of the ACA requires covered establishments to provide nutrition information to consumers in a direct, accessible, and consistent manner, typically at points of purchase, where consumers make order selections. While some ''fast food'' establishments may already have some nutrition information available to consumers in some fashion, these establishments are a subset of the establishments required to comply with the requirements of this rule, and these establishments may not be providing nutrition information to consumers in the manner required by section 4205 of the ACA.

Regarding the comment asserting that the proposed requirements somehow negate personal responsibility, we reiterate that the requirements do not tell consumers what they should or should not eat or otherwise interfere with a consumer's ability to purchase foods. In fact, as we noted previously, this rule requires covered establishments to provide accurate nutrition information to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices.

(Comment 3) Some comments addressed concerns related to enforcement. One comment expressed concern that the proposed rule did not set forth a clear ''chain of liability'' for food that is misbranded under the rule and related provisions of the FD&C Act, specifically sections 201(n), 403(a), or 403(q) of the FD&C Act. The comment stated that it is unclear whether FDA might impose vicarious liability on the franchisor or licensor of a restaurant for such misbranded food, particularly where the franchisor or licensor retains power over the menus and menu boards used by the restaurants. The comment also expressed concern that restaurants that ''unwittingly 'misbrand' their menu offerings'' will be held liable for their food that is misbranded under this rule and related provisions of the FD&C Act.

(Response 3) Persons exercising authority and supervisory responsibility over a restaurant or similar retail food establishment can be held responsible for violations under the FD&C Act. See *United States* v. *Park,* 421 U.S. 658, 659 (1978). (''The Act imposes upon persons exercising authority and supervisory responsibility reposed in them by a business organization not only a positive duty to seek out and remedy violations but also, and primarily, a duty to implement measures that will insure that violations will not occur . . . .'') (citing *United States* v. *Dotterweich,* 320 U.S. 277 (1943)). Agency decisions regarding enforcement actions will be determined on a case by case basis.

(Comment 4) Some comments addressed issues unrelated to the specific nutrition labeling requirements of section 4205 of the ACA, such as labeling of genetically engineered foods, allergens, gluten, food additives (including preservatives), artificial sweeteners, ingredients, pesticides, and organic foods; labeling to indicate whether a food has been irradiated; labeling of alcohol as a toxin; labeling the country of origin; and labeling the ''gender of meat products.''

(Response 4) Section 4205 of the ACA requires covered establishments to provide certain nutrition information for standard menu items. It does not address the labeling issues raised in these comments. Therefore, we do not address these issues in this document.

(Comment 5) Some comments directed to what establishments would be covered by the rule pointed to a report submitted by a U.S. House of Representatives Appropriations Committee explaining an appropriations bill for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies for fiscal year 2012 (Ref. 9). The comments quoted an excerpt from the report (''. . . and the Committee believes that the FDA should define the term restaurant to mean only restaurants doing business marketed under the same name or retail establishments where the primary business is the selling of food for immediate consumption . . .'') to signify Congressional intent on the scope of establishments subject to section 4205 of the ACA or as evidence supporting their own recommendations regarding the establishments that should be covered by the rule. (We note that some comments reported the date of the report as June 3, 2011, and one comment reported the date of the report

as May 27, 2011. We identified a report dated June 3, 2011 (Ref. 9), but did not identify a report dated May 27, 2011. For the purpose of this document, we assume that the comments are referring to the report dated June 3, 2011.)

(Response 5) We disagree that an Appropriations Committee report from a Congress subsequent to the Congress that passed section 4205 of the ACA can be used as evidence of the intent of the previous Congress that passed section 4205. The Appropriations Committee report cited by the comments is dated after the ACA was passed, so it is not part of the relevant legislative history and carries no interpretive weight on this issue (see, *e.g., Bruesewitz* v. *Wyeth,* 131 U.S. 1068, 1081 (2011)).

IV. Comments and FDA Response on Proposed Conforming Amendments

A. Section 11.1(g)—Electronic Signatures

Proposed § 11.1(g) (21 CFR 11.1(g)) would provide that 21 CFR part 11 regarding electronic signatures does not apply to electronic signatures obtained under the voluntary registration provision for covered restaurants and similar retail food establishments at proposed § 101.11(d).

We received no comments on this proposed provision and are finalizing it without change.

B. Sections 101.9(j)(1)(i), (j)(2) and (j)(3)—Nutrition Labeling of Food

Our proposed amendment to § 101.9(j)(1)(i) would specify that claims or other nutrition information subject the food to the nutrition labeling provisions of § 101.11 as well as § 101.9 or § 101.10 (nutrition labeling of restaurant foods), as applicable.

Our proposed amendments to § 101.9(j)(2) and (j)(3) would change the introductory text of paragraphs (j)(2) and (j)(3) to add the phrase ''Except as provided in § 101.11, food products that are:''.

We received no comments on these proposed provisions and are finalizing them without change. However, we also are adding a conforming amendment to add the phrase ''Except as provided in § 101.11'' to the beginning of the first sentence in § 101.9(j)(4). As with § 101.9(j)(2) and (j)(3), § 101.9(j)(4) needs to be revised to exclude standard menu items sold in covered establishments and reference the special labeling requirements for those foods in § 101.11 (see § 101.11(b)(2)(ii)(B)).

C. Section 101.10—Nutrition Labeling of Restaurant Foods Whose Labels or Labeling Bear Nutrient Content Claims or Health Claims

Our proposed amendment to § 101.10 would provide that the information in the written nutrition information required by § 101.11(b)(2)(ii)(A) for standard menu items that are offered for sale in covered establishments (as defined in § 101.11(a)) will serve to meet the requirements of § 101.10.

We received no comments on this proposed provision. Given our removal of the term ''restaurant food'' and our revision of the term ''restaurant-type food'' in § 101.11, we are adding a conforming amendment to ensure that the use of the term ''restaurant foods'' in § 101.10, which predates the ACA, is not confusing. We are inserting three sentences between the current first and second sentences of § 101.10, to clarify that the scope of § 101.10 includes those foods described in section 403(q)(5)(A)(i) and (ii) of the FD&C Act. These sentences describe that, for the purposes of § 101.10, restaurant food includes two categories of food. The first category of food is that which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments. The second category of food is that which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in the first category, and which is offered for sale to consumers but not for immediate consumption in such establishment and which is not offered for sale outside such establishment. This scope is reflected in numerous prior Agency statements, including in the preamble to our final rule entitled ''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food'' (58 FR 2302, 2386, January 6, 1993), and in our 2008 ''Guidance for Industry: A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods'' (Ref. 10). This change does not alter the meaning or applicability of § 101.10.

V. Key Terms That FDA Proposed To Define (Proposed § 101.11(a))

To establish the scope of establishments, labeling, and food covered by section 4205 of the ACA, we proposed to define key terms (proposed § 101.11(a)). We also proposed to establish that the definitions in section 201 of the FD&C Act apply when used in § 101.11 (proposed § 101.11(a)). We received no comments regarding the use of statutory definitions in section 201 of the FD&C Act, and we are finalizing that provision without change.

In the next section of this document, we discuss the final definitions and related comments, organized into three categories: (1) Terms related to the scope of establishments covered by the rule, (2) the terms menu and menu board, and (3) terms related to foods covered. This organization is consistent with our discussion of our proposed terms in the preamble to the proposed rule.

VI. Comments and FDA Response on the Proposed Definitions of Terms Related to the Scope of Establishments Covered by the Rule (Proposed § 101.11(a))

A. Introduction

To specify establishments that would be subject to the nutrition labeling requirements of section 4205 of the ACA, we proposed to define ''covered establishment'' to mean a *restaurant or similar retail food establishment* that is a part of a chain with 20 or more *locations doing business under the same name* (regardless of the type of ownership, *e.g.,* individual franchises) and *offering for sale substantially the same menu items,* as well as a restaurant or similar retail food establishment that is registered to be covered under section 403(q)(5)(H)(ix) of the FD&C Act. (Emphasis added).

Importantly, the definition of ''covered establishment'' includes several terms, identified in italics, that are defined in the rule. In addition, the proposed definition of one of these terms—*i.e.,* ''restaurant or similar retail food establishment''—includes other terms we proposed to define—*i.e.,* ''restaurant food'' and ''restaurant-type food.'' Thus, any revisions we make to the proposed definitions of any of these terms may affect whether a particular establishment is a ''covered establishment'' for the purposes of this rule. As discussed more fully in sections VI.B, VI.C, VI.D, VI.E, and VI.F:

- We have revised the definition of ''restaurant or similar retail food establishment'' to mean a retail establishment that offers for sale restaurant-type food, except if it is a school as defined in 7 CFR 210.1 or 220.2;
- We have revised the definition of the term ''restaurant-type food'' to focus on the food most like the food offered for sale in restaurants;

• We are adding a definition of ''locations'' to clarify our interpretation of ''part of a chain with 20 or more locations'';

• We have revised the definition of ''doing business under the same name'' so that the term ''name'' refers to either (1) the name of the establishment presented to the public or (2), if there is no name of the establishment presented to the public (*e.g.,* an establishment with the generic descriptor ''concession stand''), the name of the parent entity of the establishment; and

• We have revised the definition of ''offering for sale substantially the same menu items'' to add a qualitative description of the number of menu items that must be shared in order for the criterion of ''offering for sale substantially the same menu items'' to be met.

We proposed to define the term ''gross floor area'' because we proposed that it be used in the definition of restaurant or similar retail food establishment. While we received comments on this proposed definition, as discussed in section VI.B.2 the definition of restaurant or similar retail food establishment in this rule no longer considers gross floor area. Therefore, we are deleting the proposed definition of ''gross floor area'' because it is no longer relevant to the scope of establishments covered by this rule.

B. Restaurant or Similar Retail Food Establishment

1. The Proposed Definition

Proposed § 101.11(a) would define ''restaurant or similar retail food establishment'' as a retail establishment that offers for sale restaurant or restaurant-type food, where the sale of food is the primary business activity of that establishment. Proposed § 101.11(a) would provide that the sale of food is the retail establishment's primary business activity if the establishment presents itself, or has presented itself publicly as a restaurant (primary purpose 1), or a total of more than 50 percent of that retail establishment's gross floor area is used for the preparation, purchase, service, consumption, or storage of food (primary purpose 2). (See Figure 1 in the proposed rule (76 FR 19192 at 19201), in which we coined the terms ''primary purpose 1'' and ''primary purpose 2.'' We did not include these coined terms in the regulatory text of the definition. In this document, we are using these coined terms to simplify the discussion. We also are coining the term ''primary business test'' to simplify the discussion of the criterion for the primary business activity of the establishment.) Under an alternative approach we discussed in the proposed rule (76 FR 19192 at 19197) (the alternative revenue approach), ''primary purpose 2'' would be that more than 50 percent of the retail establishment's gross revenues are generated by the sale of food rather than that more than 50 percent of the retail establishment's gross floor area is used for the preparation, purchase, service, consumption, or storage of food.

In the proposed rule (76 FR 19192 at 19198), we also discussed an alternative (the restaurant-type food alternative) in which the sale of restaurant or restaurant-type food (rather than the sale of food in general) would be the primary business activity of the establishment. Under the restaurant-type food alternative, ''primary purpose 2'' would be that a total of more than 50 percent of a retail establishment's gross floor area is used for the preparation, purchase, service, consumption, or storage of restaurant or restaurant-type food or its ingredients.

In the proposed rule (76 FR 19192 at 19198), we acknowledged that many facilities that sell restaurant or restaurant-type food are located within larger retail establishments, such as coffee shops in bookstores or concession stands in movie theaters. We considered that some of these facilities would be separate retail establishments, while others would be part of their larger retail establishments. We explained that if a facility that is inside a larger establishment is part of a chain with locations outside of the chain of the larger establishment, the facility would be considered a separate establishment. For example, if a coffee shop in a bookstore is part of a chain of coffee shops with locations outside of the chain of bookstores, the coffee shop would be considered a separate retail establishment. By contrast, if a facility is not part of a chain with locations outside of the chain of the larger establishment, the facility would be considered part of the larger establishment. Thus, a movie theater concession stand that appears only in other movie theaters in that particular chain of movie theaters would not be considered a separate establishment for the purposes of this proposed rule.

As an example of how all of the elements of the proposed definition of restaurant or similar retail food establishment fit together, movie theaters would not have met the proposed definition of restaurant or similar retail food establishment. Movie theaters usually do not present themselves as restaurants. In addition, movie theaters usually neither dedicate more than 50 percent of their gross floor area to the sale of food, nor generate more than 50 percent of their gross revenues from the sale of food. Thus, under the proposed definition of ''restaurant or similar retail food establishment,'' movie theater concession stands generally would not have been covered regardless of whether ''primary purpose 2'' is based on the percent of gross floor area dedicated to the sale of food or on the alternative revenue approach based on the percent of gross revenues from the sale of food.

In the proposed rule (76 FR 19192 at 19197 to 19199), we acknowledged that the statutory language is ambiguous with respect to the scope of establishments covered by section 4205 of the ACA, and asked for comments on:

• Whether we should use ''primary business activity,'' or a different test, as a basis for determining whether an establishment is a restaurant or similar retail food establishment;

• Whether we should use the sale of food in general, or the sale of restaurant-type food, as the criterion for ''primary business activity'';

• Whether we should use the alternative revenue approach, rather than a floor space approach, in ''primary purpose 2'';

• Whether we should choose a different number for the cutoff for the percent of gross floor area for determining the primary business activity of the retail establishment;

• Whether we should choose a different criteria for determining primary business activity, such as whether the consumer pays for admission to the establishment; and

• Whether a facility selling restaurant or restaurant-type food that is not part of a chain with locations outside of the chain of a larger retail establishment should be included within the definition of restaurant or similar retail food establishment. We particularly requested comment on this approach with respect to larger retail establishments such as movie theaters, other entertainment-type venues, and superstores that offer restaurant or restaurant-type food.

In the following paragraphs, we discuss comments on the proposed definition of ''restaurant or similar retail food establishment.'' After considering these comments, we have revised the proposed definition to eliminate the primary business test.

Importantly, the proposed definition of ''restaurant or similar retail food establishment'' included the terms ''restaurant and restaurant-type food'' and, thus, revisions to those terms also may affect whether a particular establishment is a ''restaurant or similar

retail food establishment'' for the purposes of this rule. As discussed more fully in section VI.C, we are deleting the term ''restaurant food'' throughout the rule and establishing a revised definition of ''restaurant-type food'' that better reflects the food most like the food offered for sale in restaurants.

With these changes, in this rule ''restaurant or similar retail food establishment'' means a retail establishment that offers for sale restaurant-type food, except if it is a school as defined in 7 CFR 210.2 or 220.2. Establishments such as bakeries, cafeterias, coffee shops, convenience stores, delicatessens, food service facilities located within entertainment venues (such as amusement parks, bowling alleys, and movie theatres), food service vendors (*e.g.,* ice cream shops and mall cookie counters), food take-out and/or delivery establishments (such as pizza take-out and delivery establishments), grocery stores, retail confectionary stores, superstores, quick service restaurants, and table service restaurants would be restaurants or similar retail food establishments if they sell restaurant-type food.

2. Primary Business Test

(Comment 6) A few comments generally opposed having any primary business test within the definition of ''restaurant or similar retail food establishment.'' One of these comments recommended that the primary purpose of the definition be related to ''whether the establishment optimizes the nation's health through their food distribution channels, rather than a profit/commerce approach.'' This comment acknowledged that a ''profit/commerce approach'' may be more tangibly measured but believed that the definition of restaurant or similar retail food establishment should reflect what the comment considered to be the purpose of the ACA: To inform consumers on healthy food choices. Another comment considered that the floor space test we proposed as ''primary purpose 2'' is not a rational basis for defining a restaurant or similar retail food establishment. Another comment asserted that both the proposed definition of ''restaurant or similar retail food establishment'' and the ''alternative revenue approach'' would have covered grocery stores but not superstores, putting grocery stores at a competitive disadvantage.

One comment recommended that we define a restaurant or similar retail food establishment as any chain establishment selling restaurant or restaurant-type food. The comment asserted that this broader interpretation is consistent with the language in the statute. The comment pointed out that the statute does not include text to suggest that in order to qualify as a retail food establishment, an entity must have the sale of food as its primary business activity.

One comment recommended that the definition cover all of the establishments exempted from nutrition labeling by the NLEA. Some comments referred to examples of covered establishments that we had included in our draft implementation guidance (which we withdrew on January 25, 2011) and agreed that these types of establishments should be covered by the rule. The examples in the draft implementation guidance included table service restaurants, quick service restaurants, coffee shops, delicatessens, food take-out and/or delivery establishments (*e.g.,* pizza take-out and delivery establishments), grocery stores, convenience stores, movie theaters, cafeterias, bakeries/retail confectionary stores, food service vendors (*e.g.,* lunch wagons, ice cream shops, mall cookie counters, and sidewalk carts), and transportation carriers (*e.g.,* airlines and trains). These examples reflected the establishments that sell certain food previously exempted from nutrition labeling by the NLEA under sections 403(q)(5)(A)(i) and (ii) of the FD&C Act, including those mentioned in § 101.9(j)(2) and (j)(3) as well as some additional examples (*i.e.,* similar food served in coffee shops, grocery stores, and movie theaters). Some of the establishments that would have been covered under the draft implementation guidance (such as transportation carriers and facilities located within movie theaters) would be excluded under a definition that includes any primary business test presented in the proposed rule (*i.e.,* regardless of whether the criterion is the proposed criterion based on the sale of food in general or the restaurant-type food alternative based on the sale of restaurant-type food, and regardless of whether ''primary purpose 2'' relates to gross floor area or gross revenue). Other examples (such as grocery stores and convenience stores) would be excluded from coverage under the restaurant-type food alternative but not under the proposed criterion based on the sale of food in general.

Several comments recommended that we define a restaurant or similar retail food establishment using the restaurant-type food alternative. Some comments that opposed coverage of grocery and convenience stores asserted that selling prepared foods does not make grocery stores similar to restaurants or food court facilities that have on-premises consumption. According to some of these comments, the primary purpose of grocery stores is to sell packaged food, which is already labeled with nutrition information. One comment that opposed covering convenience stores considered that the proposed criterion for a primary business activity based on the sale of food in general, including prepackaged food, is an activity in which restaurants do not engage. The comment recommended that we view the phrase ''similar retail food establishment'' as a single cohesive term and define those that are in fact similar to restaurants.

Some comments opposed ''primary purpose 1'' of the proposed primary business test because it would be difficult to enforce. One comment asserted that some bowling alleys list themselves as restaurants in the phone book or have signs indicating that they serve as a restaurant, whereas others do not. The comments maintained that FDA and State and local inspectors would have to determine how many establishments in the chain present themselves as restaurants, which would make enforcement difficult.

One comment agreed with the proposed criterion for ''primary purpose 2''—*i.e.,* that greater than 50 percent of a retail establishment's gross floor area is used for the preparation, purchase, service, consumption, or storage of food. One comment asserted that the amount of floor space used for the preparation, purchase, service, consumption, or storage of food would be difficult to determine. Another comment considered that ''primary purpose 1'' is sufficient for determining whether an establishment is covered, but considered that the floor space criterion would be a more accurate approach than the alternative revenue approach if a second approach for ''primary business activity'' is needed. One comment asked us to clarify that ''gross floor area'' includes outdoor space for parks as part of the calculation of the percentage of gross floor area used for the preparation, purchase, service, consumption, or storage of food. A few comments recommended that seating areas, including outside seating, be included in the floor space.

A few comments preferred the alternative revenue approach for ''primary purpose 2.'' One comment reported that the Internal Revenue Service uses revenue to determine a business's primary activity. One comment suggested that we add to the proposed definition ''or a total of more than 50 percent of that retail establishment's revenues are generated by the sale of food.''

A few comments opposed the alternative revenue approach for ''primary purpose 2.'' These comments considered that it would be difficult for FDA and the States to ascertain the revenue of a restaurant or similar retail food establishment and the revenue may change from day to day. One comment noted that the proposed rule did not include a defined time period for revenue. Another comment asserted that basing ''primary purpose 2'' on revenue would be complicated when a primary non-food related service or good is paired with an ancillary service such as the sale of food in one price. The comment asserted that it would be difficult to distinguish or separate the percentage of the fee for the non-food related service or good from the percentage of the fee for the food.

A few comments suggested a lower cutoff (20 to 25 percent) for the alternative revenue approach but provided no rationale for the lower cutoff. One comment, which also supported the coverage of movie theaters, stated that movie theaters derive much of their revenue from food in concession stands.

Some comments agreed with our discussion in the proposed rule that a facility within a larger facility should not be considered to be a separate establishment if it is not part of a chain outside that establishment. Some comments specifically agreed that facilities located within movie theaters and other entertainment venues should not be covered by the provisions of section 4205 of the ACA. However, many comments opposed a definition of ''restaurant or similar retail food establishment'' that would exclude facilities located within a larger facility, specifically facilities in movie theaters and other entertainment venues. Some of these comments provided the following reasons for including such facilities:

- Excluding facilities located within movie theaters removes information from consumers, which defeats the very purpose of the law.
- Food in entertainment venues is high in calories and some of these venues cater to children and have many less healthy options (*e.g.,* fries, ice cream, cotton candy).
- Covering facilities located within movie theaters would not be burdensome for them because they have limited menu options and many packaged foods that have Nutrition Facts.
- Movie theaters derive large revenue from the sale of food; some much more than chain restaurants. It is irresponsible to send the message that consumption of calories in popcorn offered for sale at movie theaters is not as important as consumption of calories in menu items offered for sale at drive-through restaurants.
- Movies attract sedentary people.
- Congress intended that the law apply to movie theaters, bowling alleys, bookstore cafes, and other establishments; the phrase ''and similar retail establishments'' was used to reach beyond restaurants.
- Excluding facilities located within movies theatres and other entertainment venues is unfair to competing venues.
- Providing other services or entertainment does not affect the need for nutrition information.
- Menu labeling is feasible in venues not covered by the proposed rule. Movie theaters in California, New York City, and counties in New York are providing this information with no problem. To capriciously exempt movie theaters defeats the purpose of the law. One comment asserted that there is 98 percent compliance for menu labeling by movie theaters in New York City.
- Excluding such venues raises equal protection concerns (U.S. Const. 14 Amend. section 1 for similarly situated entities).

One comment considered that we would have to broaden the scope of covered establishments to include other places (such as bowling alleys, airlines, trains, and hotels), regardless of whether they fit the proposed definition of a restaurant or similar retail food establishment, if the rule covered establishments such as facilities located within movie theaters. This comment argued that there is no mention in the legislative history, committee reports, or Congressional floor debates of facilities located within movie theaters being covered. The comment considered that no one would associate ''chain retail food establishment'' with movie theaters because the primary purpose of going to movies or other entertainment venues is not to eat food and noted that many States and localities do not include these establishments in their laws. Another comment suggested that we add the following statement to our proposed definition: ''This definition does not include businesses or establishments that sell food incidental to their primary purpose of providing or hosting entertainment at venues such as movie and live theaters, arenas, amusement parks, sports facilities, concert venues, and other similar establishments.''

(Response 6) We have revised the definition of ''restaurant or similar retail food establishment'' to eliminate the primary business test. Most of the comments opposed one or more aspects associated with our proposal to include a primary business test, and we are persuaded by them. The comments we received were diverse and raised important considerations, including issues related to fairness; public health impact; accessibility of nutrition information; enabling informed decision-making; statutory purpose and Congressional intent; enforcement challenges; and feasibility of complying with the rule. We are convinced that any primary purpose test presented in the proposed rule will be problematic.

Congress did not define the term ''restaurant or similar retail food establishment'' in section 4205 of the ACA or elsewhere in the FD&C Act. As we stated in the proposed rule, we look to statutory context as a starting point for the regulatory definition of ''restaurant or similar retail food establishment.'' As we noted, the 1990 NLEA amendments exempted two categories of food relevant for this discussion: (1) Food ''which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments,'' (termed ''restaurant food'' in the proposed rule); and (2) food ''which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in [(1)] and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment'' (termed ''restaurant-type food'' in the proposed rule). Section 4205 of the ACA amended both of these statutory exemptions. In determining the scope of section 4205 of the ACA, we must determine which of these foods should remain wholly exempt from Federal nutrition labeling requirements and which should be covered by the new nutrition labeling requirements in this rule.

Instead of using a primary purpose test within the definition of restaurant or similar retail food establishment to set the scope of the new law, we are finalizing a broader definition of restaurant or similar retail food establishment, consistent with many of the comments. In response to concerns about overreaching in establishments that sell a significant amount of food that is not typical of food sold in restaurants, such as grocery and convenience stores (see also discussion in section VI.B.3), we are narrowing the set of food covered by removing the term ''restaurant food'' from this rule and redefining ''restaurant-type food'' to

include only the set of food described in sections 403(q)(5)(A)(i) and (ii) of the FD&C Act that is most like the food served in restaurants (see discussion in section VI.C). Retail food establishments that offer for sale this type of food are either restaurants or are relevantly similar to restaurants in that they offer for sale the kind of food that restaurants do. Therefore, the final definition focuses on those establishments that offer for sale food that is most like food served in restaurants; overall, it is generally broader than the definition provided in the proposed rule, but narrower than what we put forward in the draft implementation guidance.

Most of the comments that addressed the floor space approach or the alternative revenue approach to ''primary purpose 2'' expressed a preference for one or the other without providing strong and convincing arguments as to why their preferred alternative is superior to the alternative that they opposed. Several comments identified challenges to enforcing the rule if the definition of ''restaurant or similar retail food establishment'' included either the floor space approach or the alternative revenue approach.

We agree with several points made by the comments about facilities within entertainment venues such as movie theaters and amusement parks—*e.g.,* that providing nutrition information to consumers at such venues will make such nutrition information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices; food in entertainment venues is similar to food offered for sale in other restaurants or similar retail food establishments; and covering entertainment venues would create a level playing field. Under the revised definition of ''restaurant or similar retail food establishment,'' such facilities in entertainment venues will be covered by the rule if they offer for sale restaurant-type food and satisfy the other criteria in the definition of ''covered establishment''—*i.e.,* part of a chain with 20 or more locations, doing business under the same name, and offering for sale substantially the same menu items. Similarly, some superstores that may not have been covered under the proposed definition likewise may be considered a ''restaurant or similar retail food establishment'' under the final definition established in the rule. Under the definition of ''restaurant or similar retail food establishment'' in this rule, a superstore, like a grocery store, would be covered if it sells restaurant-type food and is part of a chain with 20 or more locations, doing business under the same name, and offering for sale substantially the same menu items. Hotel restaurants are another type of establishment that we stated generally would not have been covered under the proposed rule (76 FR 19192 at 19198), but would be covered under the final rule if they sell restaurant-type food and are part of a chain of hotel restaurants with 20 or more fixed locations, doing business under the same name, and offering for sale substantially the same menu items.

We disagree that the legislative history of section 4205 of the ACA demonstrates any express intent of Congress to exclude facilities located within entertainment venues such as movie theaters and bowling alleys from the rule. The legislative history of section 4205 of the ACA is very sparse; the section was discussed on few occasions, and when it was discussed, few specifics were mentioned, including specifics about the scope of the law.

We discuss transportation venues later in this document (see Response 27).

(Comment 7) One comment considered the proposed requirement that the sale of food be the retail establishment's primary business to be at odds with the approach taken in the proposed vending machine rule. The comment pointed out that we concluded that only 5,000 of 10,000 vending machine operators operate vending machines as their primary business, yet the proposed vending machine rule would apply to those with 20 or more machines, which includes all 10,000 of the vending machine operators.

(Response 7) The provisions of the proposed vending machine rule, including criteria for determining coverage of that rule, are not relevant to the criteria for determining coverage of this rule. Regardless, this comment is moot because the definition of ''restaurant or similar retail food establishment'' established in this rule no longer includes a primary business test.

(Comment 8) A few comments recommended that we separately define ''restaurant'' and ''similar retail food establishment.'' One of these comments recommended that we define ''restaurant'' separately from ''similar retail food establishment'' because Congress uses the word ''or'' in the phrase ''restaurant or similar retail food establishment,'' and thus ''restaurants'' and ''similar retail food establishments'' are clearly two separate things. Another comment recommended that we define a restaurant as one that uses greater than 50 percent gross floor space for preparation, purchase, service, consumption of restaurant food and a similar retail food establishment as an establishment that meets the same standard but does not present itself as a restaurant.

(Response 8) We disagree that we should separately define ''restaurant'' and ''similar retail food establishment.'' As an initial matter, while Congress does use the word ''or'' between ''restaurant'' and ''similar retail food establishment'' in some places, it also uses the word ''and'' between them in others. For example, section 403(q)(5)(H)(i) of the FD&C Act contains both constructions (''General requirements for restaurants and similar retail food establishments'' and ''the restaurant or similar retail food establishment shall disclose''). We interpret the choice of the words ''and'' and ''or'' in section 403(q)(5)(H) of the FD&C Act to be a function of appropriate grammar, not to indicate Congressional intent to conceptualize ''restaurants'' separately from ''similar retail food establishments.'' Moreover, given that the requirements in section 403(q)(5)(H) of the FD&C Act are the same for restaurants and similar retail food establishments, we see no practical reason to create separate regulatory definitions.

(Comment 9) One comment recommended that we include as part of the regulation table 1 from the proposed rule to help the public interpret the regulation.

(Response 9) In the proposed rule (77 FR 19192 at 19198 and 19199), tables 1 and 2 identify establishments that generally would, or would not, be a ''restaurant or similar retail food establishment'' for the purposes of this rule. We included these tables to demonstrate the likely impact for many establishments of the proposed and alternative criteria for a ''primary business test'' within the definition of ''restaurant or similar retail food establishment.'' The definition of ''restaurant or similar retail food establishment'' established in this rule no longer has a primary business test. Any establishment that sells restaurant-type food is a ''restaurant or similar retail food establishment'' for the purposes of this rule. Therefore, we see no value added in including such tables in this final rule.

3. Coverage of Grocery Stores and Convenience Stores

(Comment 10) Several comments recommended that grocery stores be covered. Some of these comments considered that grocery stores should be covered because they sell a great deal of food for immediate consumption. One

of these comments referred to the ''Food Marketing Institute's 2010 U.S. Grocery Shopper Trends'' (Ref. 11) as evidence that the number of consumers who express interest in supermarket ready-to-eat food is at its highest point in 4 years. One comment asserted that the law does not exempt grocery stores or take-out food.

(Response 10) We agree with these comments. Grocery stores that sell restaurant-type food and are part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items are covered by the rule.

(Comment 11) One comment argued that the plain meaning of section 4205 of the ACA precludes including grocery stores as ''restaurants and similar retail food establishments.'' The comment stated that Congress used other words elsewhere in the FD&C Act to refer to the set of establishments that include grocery stores, such as ''food retailer'' and ''retail establishment'' in section 403(q) of the FD&C Act. In addition, our regulation at 21 CFR 1.227 defines ''retail food establishment'' to include grocery stores for the purposes of food facility registration. Given that Congress chose a different term here, the comment argued that we must assume ''similar retail food establishments'' has a different meaning.

(Response 11) We disagree with this comment. We do interpret the phrase ''similar retail food establishment'' to have a different meaning than the terms ''food retailer'' and ''retail establishment'' that appear elsewhere in section 403(q) of the FD&C Act or ''retail food establishment'' in 21 CFR 1.227. Both our proposed and final definitions are different from the definitions of these other terms. If a retail food establishment does not offer for sale restaurant-type food, it would not be a ''restaurant or similar retail food establishment'' for the purposes of section 403(q)(5)(H) of the FD&C Act, even though it could be a ''food retailer'' or a ''retail establishment'' or ''retail food establishment.''

(Comment 12) One comment argues that the heading of section 4205 of the ACA, ''Nutrition Labeling of Standard Menu Items at Chain Restaurants,'' indicates that ''restaurants or similar retail food establishments'' is an ambiguous term, and should be interpreted narrowly to exclude grocery stores.

(Response 12) We disagree with this comment. First, while we recognize that the heading of a statute may be considered part of a section's legislative history, the heading is not part of the law itself (Ref. 12). Second, it is clear that the heading is not meant to describe the scope of the requirements in section 4205 of the ACA, given that section 4205 includes requirements for ''restaurants and similar retail food establishments'' and requirements for vending machine operators.

(Comment 13) One comment argued that the legislative history of section 4205 of the ACA demonstrates that grocery stores should not be included in the menu labeling requirements. The comment cited a floor speech by Senator Harkin where he favorably compares the nutrition information available in grocery stores to the lack of nutrition information available at restaurants. For example, ''It makes no sense that American consumers can go to a grocery store and find nutrition information on just about anything, but then they are totally in the dark when they go to a restaurant for dinner.'' (Ref. 13) The comment also argued that the legislative history does not include any hearing or debate indicating that we were being given authority to regulate chain grocery stores through section 4205 of the ACA.

Some comments stated that some State and local jurisdictions did not cover grocery stores. One comment remarked that State and local laws related to menu labeling referred to in the legislative history of section 4205 of the ACA did not cover grocery stores. Specifically, the comment mentions that the New York City Health Code provisions on menu labeling, which the comment characterizes as the first and most extensively discussed law cited by Senator Harkin, does not regulate supermarkets.

(Response 13) We disagree that the legislative history demonstrates that grocery stores should not be included in the nutrition labeling requirements of this rule. First, the most straightforward interpretation of Senator Harkin's statements is that the food in grocery stores he had in mind was packaged food already required to bear nutrition information under Federal law.

Second, the fact that none of the State or local jurisdictions with menu labeling requirements explicitly covered grocery stores does not mean that Congress did not intend to cover grocery stores under the Federal law. Many State and local jurisdictions with menu labeling requirements predating the ACA did not cover self-service food or food on display, which is most likely to be the type of food in grocery stores covered by this rule. However, it is clear that Congress intended for self-service food and food on display to be covered, because section 403(q)(5)(H)(iii) explicitly establishes statutory requirements specific to self-service food and food on display. In addition, for at least some local governments, including New York City, the regulation of grocery stores fell outside of their jurisdiction (Ref. 14). So, the fact that grocery stores were not covered by New York City cannot be assumed to be a choice by local authorities.

Finally, we recognize that the legislative history of section 4205 of the ACA does not include any hearing or debate indicating specifically mentioning chain grocery stores. However, this does not imply that Congress intended for grocery stores to be excluded. As already noted, the legislative history of section 4205 of the ACA is very sparse; the section was discussed on few occasions, and when it was discussed, few specifics were raised, including specifics about the scope of the law. The comment does not provide evidence to the contrary. Our final rule represents a reasonable interpretation of the statute, given the language of section 4205 of the ACA and the scant legislative history.

(Comment 14) Some comments asserted that if Congress had intended broad application, it would have overhauled 21 U.S.C. 343(q)(5)(A)(i) and (ii) of the FD&C Act rather than letting those stand and adding 21 U.S.C. 343(q)(5)(H). Further, these comments stated that if Congress had wanted to include all establishments exempted by the NLEA, it would have cross-referenced to the NLEA exemption or just removed the exemption.

(Response 14) We agree with some of these comments and disagree with others. We agree that Congress did not intend for all establishments exempted by the NLEA to be covered by section 4205 of the ACA. Under the rule, there are many establishments, including establishments that meet the regulatory definition of restaurant or similar retail food establishment, that will not be covered. For example, food described in section 403(q)(5)(A)(i) of the FD&C Act served in certain sit-down restaurants that are not part of a chain of 20 or more locations will continue to be exempt from the Federal nutrition labeling requirements in sections 403(q)(1) to (4). In addition, section 403(q)(5)(A)(i) and (ii) of the FD&C Act continue to exempt all food that is described in sections 403(q)(5)(A)(i) and (ii), including food offered for sale in restaurants and similar retail food establishments, from the nutrition labeling requirements in sections 403(q)(3) and (4). Therefore, irrespective of the breadth of section 403(q)(5)(H) of the FD&C Act, Congress's amendment to sections 403(q)(5)(A)(i) and (ii) leaves a large portion of the exemption intact. Congress could not

have removed the exemption in sections 403(q)(5)(A)(i) and (ii) of the FD&C Act and achieved the same result.

Instead, Congress amended sections 403(q)(5)(A)(i) and (ii) of the FD&C Act to cross-reference section 403(q)(5)(H). The cross-references to section 403(q)(5)(H) of the FD&C Act in sections 403(q)(5)(A)(i) and (ii) indicate that the requirements in 403(q)(5)(H) must apply to at least a subset of those foods described in both sections 403(q)(5)(A)(i) and (ii). Congress did not provide a statutory definition of ''restaurant or similar retail food establishment'' in section 403(q)(5)(H) of the FD&C Act, leaving ambiguity in the statute as to the breadth of the set of establishments covered. Our definition of restaurant or similar retail food establishment is a reasonable interpretation of this ambiguous term, and is consistent with section 4205's amendments to section 403(q)(5)(A)(i) and (ii) of the FD&C Act.

(Comment 15) One comment argued that the restaurant industry supported section 4205 of the ACA, because the law would provide them with a nationally uniform regulatory scheme. The comment asserted that grocery stores ''did not ask for this law,'' and should therefore not be covered.

(Response 15) In general, whether an industry asks to be regulated is not determinative of whether that industry should be regulated. In addition, grocery stores are increasingly offering for sale restaurant-type food, including food for immediate consumption that is prepared and processed on the premises.

(Comment 16) A few comments maintained that there is too much variability in grocery store food because food is seasonal and grocery stores make prepared food from food in the store. Some comments also noted that some grocery stores offer unique menu items, such as a unique chicken salad based on the personal recipe of a chef at a particular grocery store's location, that are not available at all grocery stores in the chain. These comments asserted that it would be difficult to calculate the nutrient information if grocery stores were covered under the final rule.

(Response 16) A grocery store is required to make calorie declarations for its standard menu items if it meets the definition of ''covered establishment'' in this rule; including, in relevant part, that the grocery store is ''offering for sale substantially the same menu items'' as other grocery stores in the chain (see section VI.F for discussion on ''offering for sale substantially the same menu items''). However, if a food is not routinely included on a menu or menu board or routinely offered as a self-service food or food on display at a covered establishment, it is not a standard menu item at that establishment and therefore not covered by this rule (see section VIII.B for discussion on the definition of standard menu item). For example, if a food's ingredients and recipe changes daily based on food available in the store, it is likely that such food would not be a standard menu item. However, for food offerings that are standard menu items, even if unique to only one location in the chain, a covered establishment has many options for determining nutrient content, including, for example, calculating the required nutrient information from the recipe for the food offering using nutrient databases (see § 101.11(c)). Per the statute, in those cases where seasonal availability is limited to less than 60 days, the food offering may be exempt from the nutrition labeling requirements of this rule as a temporary menu item or a self-service food and food on display that is offered for sale for less than a total of 60 days per calendar year.

(Comment 17) One comment maintained that menu labeling is needed in small grocery stores and convenience stores because of the disparity in low-income neighborhoods that do not have many large grocery stores or superstores but do have small grocery stores and convenience stores. According to the comment, grocery stores, convenience stores, and drug store chains have expanded their businesses to include ready-to-eat food offerings. The comment maintained that these establishments are in direct competition with restaurants and have grown so rapidly over the past decade that some are being called ''grocerants.''

(Response 17) Small grocery stores and convenience stores are covered by the rule if they sell restaurant-type food and are part of a chain with 20 or more locations, doing business under the same name, and offering for sale substantially the same menu items.

(Comment 18) One comment considered that grocery stores should not be covered by the menu labeling requirements because they do not have menus and menu boards.

(Response 18) We disagree with this comment. First, the comment suggests that no grocery stores have menus or menu boards. However, some grocery stores do have menus and menu boards, including for example, menus and menu boards for sandwiches that are prepared upon the consumer's request. Second, the comment implies that a restaurant or similar retail food establishment must have a menu or menu board in order to be covered by this rule. This is not the case. Consistent with section 403(q)(5)(H) of the FD&C Act, this rule requires that covered establishments provide certain nutrition information for standard menu items, even the standard menu items that do not appear on menus or menu boards. For example, section 403(q)(5)(H)(iii) of the FD&C Act requires nutrition labeling for standard menu items that are self-service foods and foods on display, irrespective of whether they are listed on a menu or menu board.

4. Confectionery Stores

(Comment 19) A few comments recommended that confectionery stores not be covered because they do not sell restaurant food. According to one of these comments, most candy sold in retail confectionery stores is not generally consumed immediately where purchased or while walking away. Instead, the comment stated, most candy sold in retail confectionery stores is either prepackaged (*e.g.,* boxed chocolates) or selected by the consumer and placed in a box or other packaging for consumption at a later time. Thus, according to this comment, food served in retail confectionery stores without facilities for consumption on the premises would continue to be covered by the nutrition labeling requirements in § 101.9. Another comment acknowledged that some confectionary stores do sell some restaurant-type foods, such as chocolate from display cases, shakes, and specialty items dipped in chocolate, but that the primary focus of the business was the sale of packaged food such as ''gift box'' packaged chocolates.

(Response 19) We disagree that confectionery stores, as a class of retail food establishments, should not be covered. Based on these comments, some foods sold in some confectionery stores are restaurant-type foods. As discussed in section VI.C, we are establishing a revised definition of ''restaurant-type food'' that would cover food that is usually eaten on the premises, while walking away, or soon after arriving at another location (see Response 24). A prepackaged box of candy sold in a confectionery store is not likely to be a restaurant-type food, because a box of candy is not usually eaten on the premises, while walking away, or soon after arriving at another location. However, individual pieces of candy sold to a consumer from a display case, shakes, and specialty items dipped in chocolate likely would be restaurant-type foods, because they are generally consumed on the premises, while walking away, or soon after arriving at

another location. Under this rule, a confectionery store that sells restaurant-type food would be covered if it is part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items. We note that the only foods covered by this rule in a covered establishment are restaurant-type foods that are standard menu items.

5. Facilities Within Facilities

(Comment 20) One comment asked us to clarify that the independent franchise restaurant that operates within an amusement park is liable for adherence to the final regulation, not the park. The comment maintained that the park would have no way of knowing if the franchisee is compliant.

(Response 20) The covered establishment bears the responsibility to comply with the rule. In addition, see Response 3.

6. Schools

(Comment 21) One comment asked us to clarify whether a school food service contractor that uses a central kitchen or cooks the same food for 20 schools would be covered. One comment stated that these establishments should provide calories on menu boards, online menus, and menus sent home to parents.

(Response 21) We have decided not to include schools in the definition of ''restaurant or similar retail food establishment'' for the purposes of this rule. As previously discussed (see Response 6) Congress did not define the term ''restaurant or similar retail food establishment'' in section 4205 of the ACA or elsewhere in the FD&C Act. The term is ambiguous, and we look to statutory context as a starting point for our regulatory definition. As discussed in section I of this document, while the NLEA required that the labeling of many foods bear nutrition information, it exempted certain food from such nutrition labeling requirements, including food that is ''served in restaurants or other establishments in which food is served for immediate human consumption'' (section 403(q)(5)(A)(i) of the FD&C Act). In FDA's regulations implementing the NLEA, we included schools among the list of examples of ''other establishments in which food is served for immediate human consumption'' (§ 101.9(j)(2)) Section 4205 of the ACA amended this statutory exemption, among others, to account for new nutrition labeling requirements for standard menu items in restaurants and similar retail food establishments. Therefore, we must determine whether standard menu items in schools should remain wholly exempt from FDA nutrition labeling requirements or whether they should be eligible to be covered by the new nutrition labeling requirements in this rule.

Traditionally, the U.S. Department of Agriculture (USDA) has exercised a primary role in setting the standards for foods served in schools through school lunch and breakfast programs. USDA regulates such foods, under various Federal statutes, including the Child Nutrition Act of 1996 and the Richard B. Russell National School Lunch Act. Given the traditional and long-standing role of USDA in setting standards, including nutrition requirements, for foods served in schools through school lunch and breakfast programs, as established by Federal legislation and implemented by Federal Agencies, we conclude that it is reasonable to interpret the term ''restaurant or similar retail food establishment'' to not include schools. Therefore, we have revised the definition ''restaurant or similar retail food establishment'' to mean a retail establishment that offers for sale restaurant-type food, except if it is a school as defined in 7 CFR 210.2 or 220.2.

C. Restaurant Food and Restaurant-Type Food

A key term in the final definition of ''restaurant or similar retail food establishment'' is the term ''restaurant-type food.'' The terms ''restaurant food'' and ''restaurant-type food'' also were important to the proposed definition of ''restaurant or similar retail food establishment.'' Proposed § 101.11(a) would define ''restaurant food'' as food that is served in restaurants or other establishments in which food is served for immediate human consumption, *i.e.,* to be consumed either on the premises where that food is purchased or while walking away; or which is sold for sale or use in such establishments. (As a typographical error, the proposed rule incorrectly stated ''where that the food is purchased'' rather than ''where that food is purchased.'') Proposed § 101.11(a) would define ''restaurant-type food'' as food of the type described in the definition of ''restaurant food'' that is ready for human consumption, offered for sale to consumers but not for immediate consumption, processed and prepared primarily in a retail establishment, and not offered for sale outside of that establishment.

In the following paragraphs, we discuss comments on these proposed definitions. After considering comments, we are deleting the proposed definition of ''restaurant food'' and establishing a revised definition of ''restaurant-type food'' that better reflects the food most like the food offered for sale in restaurants. As conforming amendments, we are deleting the term ''restaurant food'' from other proposed definitions that had included this term—*i.e.,* the proposed definitions for ''food on display,'' ''restaurant or similar retail food establishment,'' ''self-service food,'' and ''standard menu item.''

(Comment 22) One comment recommended that food be covered if prepared for immediate human consumption regardless of whether consumers choose to consume on or off the premises. The comment recommended that we remove the term ''walking away'' from the definition of restaurant food because it would be clearer to state simply that foods that are served in restaurants or similar retail food establishments and are prepared for immediate human consumption are covered, whether customers choose to consume them on or off the premises. The comment considered that whether foods are actually consumed on or off the premises should not be a determining factor as to whether a food or facility is covered by the rule. The comment asked us to clarify that food from facilities serving take-away food that meet the other criteria are covered.

(Response 22) We decline the specific suggestion that we replace our proposed criterion that food may be ''consumed either on the premises where the food is purchased or while walking away'' with a criterion mentioning that consumers may consume the food ''on or off the premises.'' The comment did not disagree that restaurant food should include food that is consumed while walking away but rather suggested communicating this differently.

While restaurants do offer for sale food that is consumed off the premises, in general that food is consumed while walking away or upon arriving at another location. Other foods, like groceries, are also consumed ''off the premises'' of the store that sells them (*e.g.,* a grocery or convenience store), but they are often consumed at a later time or over a period of days. Our aim is to cover the food most like the food offered for sale in restaurants, and not food that is more similar to food traditionally thought of as groceries. Therefore, the phrase ''on or off the premises'' is too broad for our final definition of restaurant-type food.

In general, take-away food is consumed while walking away or upon arriving at another location. Therefore, take-away food is likely to be ''restaurant-type food,'' and retail

establishments that offer for sale take-away food are likely to meet the definition of restaurant or similar retail food establishment. Take-away food that satisfies the definition of ''restaurant-type food'' established in this rule would be subject to the nutrition labeling requirements of this rule if it is a standard menu item that is offered for sale in a covered establishment.

(Comment 23) One comment recommended that the phrase ''not offered for sale outside that establishment'' be deleted from the definition of restaurant food because some restaurants market frozen meals from their restaurants.

(Response 23) We are retaining the phrase ''not offered for sale outside such establishment'' in the definition of restaurant-type food. This phrase comes from section 403(q)(5)(A)(ii) of the FD&C Act. FDA previously has interpreted this phrase (see 58 FR 2079 at 2146 (January 6, 1993)). The frozen meals described by the comment appear to be packaged foods. Most packaged foods are subject to the labeling requirements of § 101.9. The sale of such packaged, frozen food outside of a restaurant, *e.g.,* in a grocery store, will not affect whether the food in a restaurant is covered by this rule.

(Comment 24) One comment urged us to remove the term ''restaurant-type food'' from the rule and recognize that the sale of food to consumers for immediate consumption is a primary distinguishing factor of a restaurant. The comment contended that our definition of restaurant or similar retail food establishment is overly broad because it includes an establishment that sells not only restaurant food but also restaurant-type food. The comment maintained that we did not explain our rationale for including restaurant-type food in the proposed rule, especially when our existing regulation on restaurants refers only to restaurant food.

A few comments were concerned that because of the definition of restaurant-type food grocery stores would have to label prepared foods for immediate consumption as well as every loaf of bread, roll, cookie and deli item except cold cuts; these comments estimated that approximately 6,400 service deli, prepared foods, and bakery items would be included, which would be very costly. One comment contended that the increase in cost may limit the items that grocery stores would carry, which would limit sales growth. According to a few comments 95 percent of items in grocery stores have Nutrition Facts and the costs to cover the remaining 5 percent vastly outweighs benefits.

(Response 24) We agree that sale of food to consumers for immediate consumption is a common characteristic of restaurants but disagree that it follows that only ''restaurant food'' is relevant to this rulemaking. In the proposed rule, we explained that section 4205 of the ACA amended both sections 403(q)(5)(A)(i) and (ii) of the FDA&C Act. Under section 403(q)(5)(A)(ii) of the FD&C Act, except as provided in section 403(q)(5)(H)(ii)(III) of the FD&C Act (*i.e.,* the requirement for written nutrition information for food covered by this rule) the nutrition labeling requirements of section 403(q)(1), (2), (3), and (4) of the FD&C Act shall not apply to food which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in section 403(q)(5)(A)(i), and which is offered for sale to consumers *but not for immediate human consumption* in such establishment and which is not offered for sale outside such establishment (emphasis added). To implement the phrase ''except as provided in section 403(q)(5)(H)(ii)(III)'' of the FD&C Act, some set of food described in section 403(q)(5)(A)(ii)—that is not for immediate consumption—is covered by this rule.

We acknowledge that the proposed definition of restaurant-type food includes some foods that are sold in grocery or convenience stores that are not generally offered for sale in restaurants, foods that are more like groceries, and we have amended that definition in the final rule. After considering all of the comments directed to the proposed definitions of ''restaurant food'' or ''restaurant-type food,'' in addition to the comments related to the scope of the rule more generally, given the relationship between these terms and the definition of restaurant or similar retail food establishment, we are convinced that this rule should cover only those foods described in sections 403(q)(5)(A)(i) and (ii) of the FD&C Act that are most like the food sold in restaurants and should not cover foods that are more commonly considered to be groceries. Therefore, we are deleting the proposed definition of ''restaurant food'' and establishing a revised definition of ''restaurant-type food'' that reflects the food most like the food offered for sale in restaurants. Under that new definition, restaurant-type food means food that is (1) usually eaten on the premises, while walking away, or soon after arriving at another location; and (2) either (i) served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments; or (ii) processed and prepared primarily in a retail establishment, ready for human consumption, of the type described in (i), and offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment. The first part of this definition focuses on the food most like the food offered for sale in restaurants, while the second part of this definition reflects the statutory context of sections 403(q)(5)(A)(i) and (ii) of the FD&C Act. The new definition includes food for immediate consumption at a sit-down or quick service restaurant; food purchased at a drive-through establishment; take-out and delivery pizza; hot pizza at grocery and convenience stores that is ready to eat; pizza slice from a movie theater; hot buffet food, hot soup at a soup bar, and food from a salad bar; foods ordered from a menu/menu board at a grocery store intended for individual consumption (*e.g.,* soups, sandwiches, and salads); and self-service foods and foods on display that are intended for individual consumption (*e.g.,* sandwiches, wraps, and paninis at a deli counter; salads plated by the consumer at a salad bar; cookies from a mall cookie counter; bagels, donuts, rolls offered for individual sale). Foods that are similar to grocery items that may be ready for immediate consumption but that consumers usually store for use at a later time or customarily further prepare would not be included within the meaning of ''restaurant-type food.'' Foods that we therefore would not consider to be within the meaning of ''restaurant-type food'' include foods to be eaten over several eating occasions or stored for later use (*e.g.,* loaves of bread, bags or boxes of dinner rolls, whole cakes, and bags or boxes of candy or cookies); foods sold by weight that are not self-serve and are not intended solely for individual consumption (*e.g.,* deli salads sold by unit of weight such as potato salad, chicken salad), either prepacked or packed upon consumer request; and foods that are usually further prepared before consuming (*e.g.,* deli meats and cheeses).

(Comment 25) One comment asked us to clarify that only food offered ''for sale'' in a restaurant or similar retail food establishment should be considered in determining whether an establishment is a covered establishment. The comment noted that the statute expressly limits the

application of food labeling to items that are ''offered for sale,'' and considered that the menu labeling regulations should adopt a similar limitation.

(Response 25) The rule only applies to food offered for sale.

D. Part of a Chain With 20 or More Locations

In the proposed rule (76 FR 19192 at 19195), we noted that we did not propose a definition of the statutory criterion ''part of a chain with 20 or more locations'' and that we were assuming the common meaning of the words in the phrase. However, we requested comment on whether the phrase should be defined in the final rule, and particularly on whether the terms ''chain'' and ''location'' should be defined in context of the various types of corporate or other business arrangements that may be relevant, including contracting arrangements.

In the following paragraphs, we discuss comments on the terms ''chain'' and ''location.'' After considering these comments, we are adding a definition of ''locations'' to clarify our interpretation of ''part of a chain with 20 or more locations.''

(Comment 26) A few comments responded to our request for comment on the term ''chain.'' One comment recommended that we define ''chain'' as a covered establishment doing business under the same name as those that share the same name under the ownership, control, and operation of a single corporate entity. This comment considered that this is consistent with the commonly accepted dictionary definition of a chain as ''a group of enterprises or institutions of the same kind or function under a single ownership, management, or control.'' Another comment cited the following dictionary definition for ''chain'': ''A range of retail outlets which share a brand and central management, usually with standardized business methods''. This comment also cited the following dictionary definition for ''restaurant chain'': ''A set of restaurants, usually with the same name in many different locations either under shared corporate ownership or franchising agreements. Typically, the restaurants within a chain are built to a standard format and offer a standard menu.''

(Response 26) Section 4205 of the ACA covers restaurants or similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name ''regardless of the type of ownership of the locations.'' Both definitions suggested by comments refer to management structure, corporate control, and/or ownership. Because the statute directs us to disregard the type of ownership of the locations when determining whether an establishment is ''part of a chain with 20 or more locations doing business under the same name,'' neither of these definitions for the word ''chain'' is appropriate.

According to the dictionary definitions, the word ''chain'' means, among other things, ''a group of enterprises, establishments, institution, or constructions of the same kind or function linked together into a single system'' (Ref. 15), a ''series or group of things or people that are connected to each other in some way'' (Ref. 15), and ''a series of closely linked or connected things'' (Ref. 16). In section 403(q)(5)(H)(i) of the FD&C Act, Congress provides the ways in which restaurants or similar retail food establishments must be connected to or linked to each other in order to be covered by the new law: They must be doing business under the same name and offering for sale substantially the same menu items, and there must be 20 or more locations of them. Therefore, we continue to use the common meaning of the word ''chain'' and do not consider an additional regulatory definition necessary for this broad term. The statute specifies the particular criteria for the set of chains that are relevant for this rulemaking, and we provide regulatory definitions for those criteria specifically.

(Comment 27) One comment recommended that we not rely solely on the terms ''chain'' and ''location'' because some restaurants and food establishments have locations at the same address, such as a mall. The comment asked us to either use the term ''selling post'' or to clarify that the location includes chains with restaurants in the same physical building. Another comment asked us to clarify that mobile facilities (such as food trucks) are covered. Some comments noted that transportation venues have menus that look like those in sandwich shops. Other comments noted that it is feasible for transportation venues to comply with the rule.

(Response 27) We disagree that we should add the term ''selling post'' to the definition to specify restaurants and similar retail food establishments that are part of the same chain and are located in the same shopping mall or otherwise in the same physical building. However, this comment demonstrates that there is a need to define the term ''locations,'' even assuming its common meaning. Unlike ''chain,'' where a definition is unnecessary given that we are establishing definitions for more specific, relevant criteria, we are convinced that establishing a regulatory definition of ''locations'' would provide clarity and facilitate a better understanding of regulatory expectations.

The dictionaries define ''location'' to mean, among other things, ''a position or site occupied . . . a tract of land designated for a purpose'' (Ref. 17); ''an area or tract of land'' (Ref. 18); ''a place where something is or could be located; a site . . . a tract of land that has been surveyed and marked off'' (Ref. 19). This evidences that the common meaning of the word ''location'' involves a specific or fixed position on land or portion of land. For clarity, we are defining ''location'' to mean ''a fixed position or site.'' Therefore, for the purposes of determining whether an establishment is part of a chain with ''20 or more locations,'' we would consider each of the establishments occupying separate fixed positions or sites within the same shopping mall or physical building as separate establishments. One result of this definition of ''location'' is to exclude food facilities that do not have a fixed position or site, such as trains and airplanes. Additionally, mobile food operations such as food trucks without a fixed position or site are not covered by the rule.

E. Doing Business Under the Same Name

Proposed § 101.11(a) would define ''doing business under the same name'' as sharing the same name, where ''same name'' would include names that are either exactly the same, or are slight variations of each other, for example, due to the region, location, or size (*e.g.,* ''New York Ave. Burgers'' and ''Pennsylvania Ave. Burgers'' or ''ABC'' and ''ABC Express''). In the proposed rule (76 FR 19192 at 19199), we requested comment on whether the term should be understood to refer to the underlying name of ownership such as the name of the parent company, or the name of the entity conducting corporate business on behalf of the establishment, *e.g.,* the name of a contractor operating the establishment, regardless of the public name used by the individual establishment.

In the following paragraphs, we discuss comments on this proposed definition. After considering comments, we have revised the definition to clarify that the term ''name'' refers to either (a) the name of the establishment presented to the public or (b), if there is no name of the establishment presented to the public (*e.g.,* an establishment with the generic descriptor ''concession stand''),

the name of the parent entity of the establishment.

(Comment 28) Several comments supported the proposed definition. One comment recommended that the definition be broadened to include those with the same underlying name of ownership (parent company or contractor). A few comments recommended that the definition not be based on the underlying name of ownership. Based on the language of the statute, the comments considered that ''regardless of . . . ownership'' means that the ownership is not determinative and, therefore, the term should refer to the name used when doing business with the public and not the parent company, franchise owner, or other ownership entity. One comment argued that the phrase ''regardless of . . . ownership'' means that the corporate structure should not be considered when determining coverage; instead, the determining factor should be whether the name of the restaurant is the same. Another comment maintained that to include the underlying name of ownership in the definition would stifle investment in smaller locally based restaurants, *i.e.,* it would place a cap on the number of restaurants an investor or entity could have before subjecting them to menu labeling.

One comment recommended that the definition not be based on the name of the parent company because the name of the parent company has no bearing on the similarity of menu offerings. The comment argued that to do so would ignore the plain language of the statute, which clearly meant the public name of the location. One comment asserted that our proposed definition would expand the definition beyond the statutory language and Congress' express intent by covering smaller restaurant chains that offer creative menus and, thus, thwart the purpose and intent behind thoughtfully designed restaurants.

(Response 28) We agree with comments that considered that the statutory phrase ''regardless of the type of ownership of the locations'' means that the type of ownership is not determinative. We also agree that ''doing business under the same name'' should, in general, refer to the name used when doing business with the public (*e.g.,* the branded name that appears on the establishment's signage) rather than the name of the person or legal entity that owns the establishment. However, we are aware that some establishments have no specific name presented to the public. For example, concession stands in entertainment venues or cafeterias in office buildings may simply have a sign with a general descriptor, such as ''Hot Dogs'' or ''Concession Stand'' or ''Building 1 Café,'' or they may have no sign at all. In instances where there is no specific name presented to the public, we find it reasonable to conclude that the name under which they are doing business is the name of the parent entity of the facility. Consequently, we have revised the definition of the term ''doing business under the same name'' in § 101.11(a) to add that the term ''name'' refers to the name of the facility presented to the public or, if there is no name of the facility presented to the public (*e.g.,* a facility with the generic descriptor ''concession stand''), the name of the parent entity of the facility.

(Comment 29) One comment addressed the examples we included in the proposed definition of establishments doing business under the same name. As discussed in the proposed rule (76 FR 19192 at 19199), these examples include names that are slight variations on each other due, for example, to the region, location, or size. The comment asserted that it is inappropriate to imply that same name means slight variation. Another comment recommended that the rule apply to facilities in grocery stores with 20 or more locations even if the facilities' names vary from store to store.

(Response 29) We disagree that the examples we included in the proposed definition of establishments doing business under the same name are inappropriate. Establishments that are part of large chains have slight variations in the name, *e.g.,* to reflect a limited menu based on the space that the establishment occupies. For example, ''XYZ'' chain may have ''XYZ'' restaurant in a free-standing store and ''XYZ Express'' in an airline terminal, food court in a shopping mall, or grocery store. Even though the names are slight variations of each other, they are sufficiently similar that it is clear that the establishments are affiliated with one another. Generally, these establishments also have the same trade dress (*e.g.,* trade name, logo, graphics and other distinctive elements of a brand) as the other establishments in the chain.

(Comment 30) One comment recommended that we require that a chain remain covered if it initially is subject to the rule but the parent company changes the name of some locations to get below 20.

(Response 30) Individual restaurants and similar retail food establishments would be subject to the rule if they satisfy the criteria for a ''covered establishment.'' If a restaurant or similar retail food establishment satisfies all the criteria for a covered establishment, and subsequently changes its name, it must reconsider whether it continues to satisfy all the criteria for a covered establishment, including whether it ''is part of a chain with 20 or more locations doing business under the same name.'' We anticipate that the benefits to an establishment to continue to do business under the same name as other establishments in the chain will keep establishments from changing their names in order to avoid being covered by this rule.

F. Offering for Sale Substantially the Same Menu Items

Proposed § 101.11(a) would define ''offering for sale substantially the same menu items'' as offering for sale menu items that use the same general recipe and are prepared in substantially the same way with substantially the same food components, even if the name of the menu item varies (*e.g.* ''Bay View Crab Cake'' and ''Ocean View Crab Cake''). Under the proposed definition, ''menu items'' would refer to food items that are listed on a menu or menu board or that are offered as self-service food or food on display. The proposed definition would also provide that restaurants and similar retail food establishments that are part of a chain can still be offering for sale substantially the same menu items if the availability of some menu items varies within the chain.

In the following paragraphs, we discuss comments on this proposed definition. After considering comments, we have revised the definition to:

- Add a qualitative description of the number of menu items that must be shared in order for the criterion of ''offering for sale substantially the same menu items'' to be met; and
- Add a statement that having the same name may indicate, but does not necessarily guarantee, that menu items are substantially the same.

(Comment 31) Several comments supported the definition. One comment asserted that the proposed rule was not clear on what ''substantially'' the same menu items means quantitatively and suggested that it could mean anywhere between 51 and 99 percent. Another comment asked us to clarify what constitutes ''offering for sale menu items that use the same general recipe and are prepared with substantially the same food components even if the name varies.'' This comment pointed out that some restaurants in a chain may have some unique items or may vary the recipes and therefore, it is not clear if the restaurant is ''offering for sale substantially the same menu items.''

The comment gave as an example a kosher restaurant that uses the same name as non-kosher restaurants that are part of the same chain. The comment noted that due to the kosher restaurant's following of the kosher laws, the kosher restaurant may offer for sale some menu items that vary from the menu items offered for sale in a non-kosher restaurant in the chain. In addition, the comment noted that the kosher restaurant may offer for sale unique menu items, such as schwarma, that are not offered for sale in the non-kosher restaurants in the chain. This comment requested an exemption for franchise restaurants that offer specialty menu items or items altered to accommodate a specific dietary practice (*e.g.,* kosher).

One comment pointed out that menu items in chain restaurants and similar retail food establishments vary between States and within States to accommodate local tastes, even if the menu items have the same name. The comment cited chili as an example, stating that in Cincinnati it is common for chili to be made with cocoa and cinnamon thinned out with finely ground meat over spaghetti, whereas in Texas, chili is made with large chunks of meat, often with beans, served alone in a bowl.

One comment stated that some food service contractors provide clients with menus that may change daily, weekly, or monthly and with rotating cycle menus that can use up to several hundred recipes with cycle menus that vary from 3, 4, or 5 week cycles and from 5, 6, or 7 day service weeks. Due to the variability in menus in locations that rely on contract food services, the comment recommended that the definition of ''offering for sale substantially the same menu item'' be changed to ''establishments in a chain that offer standard menus comprised of menu items that use the same general recipes and are prepared in substantially the same ways with substantially the same food components, even if the name of the menu item varies.''

(Response 31) We decline to name a proportion or percentage of menu items that must be shared between establishments. Restaurants and similar retail food establishments regularly offer new and reformulated menu items in their establishments. It would be burdensome and impractical for establishments and inspectors to continually evaluate all of the establishments in the chain to count the numbers of standard menu items in common in order to determine whether a given establishment is covered. In addition, some establishments that are part of a large chain may not offer for sale all of the standard menu items offered in other locations of that chain. For example, some chains have a handful of locations in airports or other venues notated by the term ''Express'' added to the name, that sell a subset of the foods that are carried by the larger establishments in the chain. Finally, as the comments point out, some restaurants that are part of large chains have some unique or regional items or may vary recipes in a unique way. These types of minor variations should not exclude establishments from the requirements of this rule.

Based on the comments and on the considerations discussed previously in this document, we are not finalizing a specific proportion or percentage of menu items that covered establishments within a chain must share. However, we understand from the comments that our definition should speak to the number of menu items that must be shared more clearly. Therefore, we are adding a qualitative, not quantitative, description of the number of menu items that must be shared in order for the criterion of ''offering for sale substantially the same menu items'' to be met. Given the statutory language, along with the practicalities of and variations within the industry, we are adding ''offering for sale a significant proportion of menu items'' to the definition of ''offering for sale substantially the same menu items.'' For example, if establishments only share one or two menu items, those establishments would not meet the criterion of ''offering for sale substantially the same menu items.''

We recognize that some establishments in a chain may have some menu items with ingredients that vary based on regional taste or source. Some menu items may be designed or prepared to meet certain dietary practices (*e.g.,* Kosher or Halal) or contain a ''secret ingredient.'' This is why our definition of ''offering for sale substantially the same menu items'' includes the criteria ''us[ing] the same general recipe, prepared in substantially the same way, with substantially the same food components.'' By ''the same general recipe,'' we mean that the establishments share a recipe, even if one establishment subsequently tweaks that recipe due to regional tastes or dietary practices. By ''prepared in substantially the same way,'' we mean to include slight deviations from the recipe, because of, for example, food service worker variability. By ''with substantially the same food components,'' we mean to include situations where ingredients may vary based on local availability or sourcing, including those used to conform to certain dietary practices (*e.g.,* Kosher meat).

We also agree with comments that having the same name may indicate that the menu items are substantially the same, but it does not always do so. As comments pointed out, menu items that reflect regional differences may be so different that the name of the menu item sheds little light on whether the menu items use the same general recipe and are prepared in substantially the same way with substantially the same food components. For example, in some regions of the United States a menu item named ''barbecue'' may refer to a food prepared from pulled pork, whereas in other regions a menu item named ''barbecue'' may refer to a food prepared from beef ribs. Therefore, we have revised the definition to add a new sentence stating that having the same name may indicate, but does not necessarily guarantee, that menu items are substantially the same.

The definition for ''substantially the same menu items'' would also apply to establishments relying on food contractors. If such an arrangement caused menu rotations, the relevant question would still be whether those establishments are offering for sale substantially the same menu items, including whether they are selling a significant proportion of menu items that use the same general recipe and are prepared in substantially the same way with substantially the same food components, even if not necessarily at the same time. In other words, the focus is on whether the menu items are substantially the same, not on whether the menus or menu boards are substantially the same. We decline to accept the suggestion from the comment to revise the definition to include ''establishments in a chain that offer standard menus comprised of menu items that . . .'' because it reflects a misunderstanding that an establishment needs to have a menu, or a ''standard menu'' more specifically, to be covered by the new law.

(Comment 32) One comment maintained that convenience stores in a chain do not have identical business plans and the same food; the food varies per establishment and is not prepared to corporate policy as it is in restaurants.

(Response 32) As explained previously in this document, establishments can be ''offering for sale substantially the same menu items'' even if not all of their menu items are exactly the same. Depending on the extent to which the menu items vary, a convenience store may or may not meet the criterion of offering for sale

substantially the same menu items as defined in the rule.

(Comment 33) One comment described itself as a family-owned restaurant operator with 25 restaurants located entirely within a single State. Two of its restaurants also contain sushi operations, each under a different name and with entirely different menus than the larger establishment. The comment asked us to confirm that the rule would not apply to these sushi operations.

(Response 33) Based on the information in the comment, the two sushi operations do not appear to be covered by the rule because they are neither doing business under the same name (see section VI.E) nor offering for sale substantially the same menu items as 18 other establishments.

G. Authorized Official of a Restaurant or Similar Retail Food Establishment

Proposed § 101.11(a) would define ''Authorized official of a restaurant or similar retail food establishment'' as the owner, operator, agent in charge, or other person authorized by the owner, operator, or agent in charge to register the restaurant or similar retail food establishment, which is not otherwise subject to section 403(q)(5)(H) of the FD&C Act, with FDA for the purposes of § 101.11(d). (Section 101.11(d) pertains to voluntary registration to become subject to the requirements of section 403(q)(5)(H) of the FD&C Act.)

We received no comments on the proposed definition and are finalizing it without change.

H. Covered Establishment

As already noted in section VI.A, proposed § 101.11(a) would define ''covered establishment'' as a *restaurant or similar retail food establishment* that is a part of a chain with 20 or more *locations doing business under the same name* (regardless of the type of ownership, *e.g.,* individual franchises) and *offering for sale substantially the same menu items,* as well as a restaurant or similar retail food establishment that is registered to be covered under section 403(q)(5)(H)(ix) of the FD&C Act. (Emphasis added).

In the following paragraphs, we discuss general comments on this proposed definition. We are finalizing the definition of ''covered establishment'' without change, except to refer to § 101.11(d) instead of section 403(q)(5)(H)(ix) of the FD&C Act. However, as already discussed (see sections VI.B, VI.C, VI.D, VI.E, and VI.F), changes we are making to other terms (*i.e.,* adding a definition of ''location,'' revising the definition of ''restaurant or similar retail food establishment,'' revising the definition of ''restaurant-type food,'' revising the definition of ''doing business under the same name,'' and revising the definition of ''offering for sale substantially the same menu items'') affect the overall set of covered establishments.

1. General Comments on the Definition of Covered Establishment

(Comment 34) One comment considered that our proposed definition would make it conceivable for the requirements to apply to a single, completely unique ''restaurant concept'' that is owned by a chain with 20 or more other restaurants. The comment described a ''restaurant concept'' as separate and distinct operations by virtue of the individual restaurant's menu offerings or recipes, name, decor, and other distinguishing characteristics such as different dining experiences with higher quality food and different menu items that may be unrecognizable to the average diner as being operated by the larger chain. This comment also considered that applying the menu labeling requirements to these individual ''restaurant concepts'' would not be consistent with the statute or intent of Congress. Another comment expressed concern that a person who operates more than 20 chain retail food establishments and wants to start a ''new concept'' would be required to provide nutrition information if this ''new concept'' is only in one location.

(Response 34) We disagree that we need to revise the definition of a covered establishment to prevent a misinterpretation that a single, completely unique ''restaurant concept'' that is owned by a chain with 20 or more other restaurants generally would be covered by the rule. An establishment that is ''single'' and a ''completely unique restaurant concept'' is unlikely to have ''20 or more locations'' and be ''offering for sale substantially the same menu items'' as 20 or more other restaurants. Thus, such an establishment is unlikely to satisfy the criteria in the proposed definition to be a ''covered establishment'' as it is currently written. Likewise, if a person operates more than 20 chain retail food establishments and starts a ''new concept,'' that ''new concept'' establishment would not be a covered establishment unless it is part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items. We are retaining our definition, which, as we described in the proposed rule, is derived from sections 403(q)(5)(H)(i) and (xi)(I) of the FD&C Act (76 FR 19192 at 19195).

(Comment 35) One comment recommended that we revise the definition of covered establishment to use the following language from its State's regulation: ''A food establishment that: (1) Is engaged in the business of preparing and selling food items for immediate human consumption on the premises or off the premises, . . . and (2) offers for sale substantially the same menu items, utilizing menus, menu boards or food item tags, in servings that are standardized for portion size and content, and (3) is one of a group of . . . food establishments . . . that (a) operates under common ownership or control, or (b) operates as franchised outlets of a parent business, or (c) does business under the same name.'' The comment cited only those portions of its regulation relevant to the questions raised by the definition of covered establishment in our proposed rule, and used ellipses to indicate text that was in the State regulation but not being offered as part of the definition of ''covered establishment'' in this rule.

(Response 35) We disagree with this comment and are not revising the definition of ''covered establishment'' to incorporate its suggestions. Our definition of covered establishment is derived from the Federal statutory language. The only basis offered by the comment was that the suggestions are used in a State law; the comment did not state why these changes were necessary from a policy perspective or legally justified under the Federal law.

(Comment 36) One comment recommended that the rule apply to most restaurants, and not just those with more than 20 locations, possibly excluding only establishments with a very small seating capacity. The comment contended that consumers already know that fast food is ''bad for you'' and they need to know the nutrition information about the food in other restaurants.

(Response 36) This rule implements section 4205 of the ACA, which, in general, covers only restaurants and similar retail food establishments that are part of a chain with 20 or more locations. Section 4205 of the ACA allows other restaurants and similar retail food establishments to register with FDA to become subject to the Federal requirements, but it does not require them to do so.

(Comment 37) One comment asked us to clarify whether the rule would apply to foreign establishments of a particular chain that has 20 or more establishments in the United States, and also has an establishment located in a foreign location, such as Italy.

(Response 37) The rule applies to locations in the United States, including any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico. This geographic scope is consistent with the definitions of ''State'' and ''Territory'' in section 201(a) of the FD&C Act.

(Comment 38) A few comments asked us to clarify that contractors and managed food service operations would be covered if they offer for sale substantially the same menu items.

(Response 38) Whether any other specific contractor or managed food service would be subject to the rule would depend on whether it satisfied all criteria established within the definition of ''covered establishment.'' Thus, to be a covered establishment, an establishment operated by a contractor or managed food service must be a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items. We expect that some establishments operated by contractors and managed food services will satisfy all of these criteria.

2. Cooperatives

(Comment 39) Some comments addressed cooperatives and discussed multiple aspects related to the definition of ''covered establishment,'' including ''part of a chain,'' ''doing business under the same name,'' and ''offering for sale substantially the same menu items.'' One comment considered that cooperatives should not be exempt because the law expressly states ''regardless of . . . ownership.'' One comment considered that the type of ownership of grocery stores, such as a cooperative, is irrelevant to whether a store is part of a chain. This comment maintained that the law clearly requires chains operating under the same name to disclose calories, regardless of the type of ownership. This comment also maintained that grocery store cooperatives face a similar situation as that faced by independent franchise owners of chain restaurants.

Other comments generally expressed the view that cooperatives should not be covered by the rule. One comment asserted that establishments associated with the same wholesaler or cooperative should not be considered ''part of a chain'' regardless of whether they operate under the same ''banner'' or under a different ''banner.'' The comment considered that cooperatives are the opposite of chains because they are owned by individual members, operate independently, and are not bound by franchise agreements, whereas chains are centrally controlled with little say or choice by participants. The comment asked us to recognize that independent grocers are not part of a chain of 20, doing business under same name and selling the same items, even if we believe cooperatives are similar retail food establishments.

A few comments maintained that the definition for ''doing business under the same name'' does not apply to cooperatives because they are independent and exercise their independence more than franchised restaurants. According to one comment, independent retailers own, control, and operate their stores independently as customers of voluntary wholesalers and members of cooperatives. The comment explained that the food distribution system allows independent retailers to take advantage of economies of scale when procuring goods and services, as well as marketing and advertising, thus helping independent operators effectively compete with large national chain stores. The comment also explained that these entities are independently owned and operated businesses that often compete with other stores under the same banner name, and that menu items can have different general recipes and be prepared in substantially different ways with substantially different food components.

One comment asked us to recognize that members of cooperatives are not ''doing business under the same name.'' For example, the comment considered that ''Fred's Thriftway'' is not the same as ''Bob's Thriftway.'' The comment considered that ''Thriftway'' signals that these establishments are part of a cooperative but maintained that they are two different stores.

One comment contended that the term ''offering for sale substantially the same menu items'' may not apply to some foods, such as brownies or potato salad, made in grocery store cooperatives, although those foods may be offered for sale under the same name in those stores. According to the comment, ''Bob's Thriftway'' and ''Mike's Thriftway'' may both sell brownies made from the same general recipe, (*e.g.,* flour, sugar, eggs, chocolate and butter); however, because independent grocers compete with each other, each is likely to include a secret ingredient, and as a result, the brownies are not the same.

(Response 39) We agree with some comments that the type of ownership of an establishment is not relevant to whether it is covered. To be subject to the rule, a cooperative must satisfy all the criteria in the definition of ''covered establishment.'' In other words, to be subject to the rule a cooperative must be a restaurant or similar retail food establishment that sells restaurant-type food and is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, *e.g.,* individual franchises) and offering for sale substantially the same menu items. As we explain in section VI.D., we are not defining the term ''chain'' in this rulemaking. In addition, for the reasons we provide in section VI.E., we continue to define doing business under the same name to include names that are slight variations of each other. Independent businesses that are cooperatives, even those that are similarly named, are not covered establishments if, for example, they are only connected insofar as they take advantage of economies of scale when procuring goods and services, or for marketing and advertising purposes, but are not ''offering for sale substantially the same menu items.''

However, given the way cooperatives generally are structured, we do not expect that two cooperatives would be offering for sale substantially the same menu items. Unless a food such as a brownie offered for sale in Bob's Thriftway has the same general recipe, prepared in substantially the same way, with substantially the same food components as a brownie offered for sale in Mike's Thriftway, the two cooperatives' brownies would not be ''substantially the same.'' However, if Bob's Thriftway and Mike's Thriftway share a recipe such as a brownie recipe, and the only difference between the two brownie recipes is that Mike's Thriftway has added a ''secret ingredient,'' the brownies could be considered substantially the same menu item, depending on the importance of that ingredient. Note that even in this circumstance, Bob's Thriftway and Mike's Thriftway would not be ''offering for sale substantially the same menu items'' if the brownie is the only menu item that the two cooperatives share.

In addition, we note that a cooperative that is a restaurant or similar retail food establishment and does not satisfy all of the criteria to be a covered establishment, but voluntarily registers to be covered in accordance with § 101.11(d), would be subject to the rule.

I. Revisions to Several Provisions To Clarify the Applicability of the Rule to Those Restaurants and Similar Retail Food Establishments That Are Covered Establishments

This rule applies to restaurants and similar retail food establishments that satisfy the definition of ''covered establishment'' in this rule. Several provisions of the proposed rule that would apply to ''covered establishments'' used the term ''restaurant or similar retail food establishment'' rather than ''covered establishment.'' To make clear that those provisions only apply to those restaurants and similar retail food establishments that satisfy the definition of ''covered establishment,'' we are replacing the term ''restaurant or similar retail food establishment'' with ''covered establishment'' in those provisions. The affected provisions are:

- The definition of ''custom order'' (§ 101.11(a));
- The definition of ''menu or menu board'' (§ 101.11(a));
- The introductory text of § 101.11(b)(2)(ii) regarding nutrition information for a standard menu item that must be available in written form;
- The introductory paragraph of proposed § 101.11(c)(6) (which we are establishing in § 101.11(c)(3)) regarding information that must be provided to FDA substantiating nutrient information; and
- A subparagraph of proposed § 101.11(c)(6) regarding specific substantiation documentation (*i.e.,* proposed paragraph (c)(6)(ii)(D), which we are establishing as paragraph (c)(3)(ii)(D)).

We note these changes in our discussion of each of these specific provisions.

VII. Comments and FDA Response on the Proposed Definition of Menu or Menu Board (Proposed § 101.11(a))

Proposed § 101.11(a) would define ''menu or menu board'' as the primary writing of the restaurant or similar retail food establishment from which a customer makes an order selection, including, but not limited to, breakfast, lunch, and dinner menus; dessert menus; beverage menus; children's menus; other specialty menus; electronic menus; and menus on the Internet. The proposed definition would also provide that menus may be in different forms, *e.g.,* booklets, pamphlets, or single sheets of paper and that menu boards include those inside a restaurant or similar retail food establishment as well as drive-through menu boards at restaurants or similar retail food establishments.

In the proposed rule, we stated that given the importance for all consumers to have access to nutrition information when making order selections, ''primary writing'' should be interpreted from a consumer's vantage point (76 FR 19192 at 19202). For example, while a printed menu may be the ''primary writing'' of a restaurant used by a customer ordering food while dining inside the restaurant itself, a menu mailed as a flyer to another customer's home could be the ''primary writing'' of the restaurant used by that customer ordering take-out or delivery from the same restaurant. Both the printed menu and the menu flyer would meet the definition of ''menu'' or ''menu board'' under proposed § 101.11(a).

In the following paragraphs, we discuss comments on this proposed definition. We have revised the definition by replacing the term ''restaurant or similar retail food establishment'' with ''covered establishment'' in three locations in the definitions for clarity (see explanation in section VI.I). We are also including factors used to determine whether a writing is or is part of the primary writing from which a consumer makes an order selection.

(Comment 40) Many comments supported the proposed definition and agreed that ''primary writing'' should be interpreted from the perspective of consumers, so that each writing of the establishment that is the primary writing used by consumers in making order selections would be considered a menu or menu board. Several comments asserted that consumers need to see calorie information when making order selections in order for the information to be useful to them. One comment noted that Congress did not intend for covered establishments to only provide calorie declarations on a single medium in each establishment, as evidenced by the fact that section 4205 of the ACA requires calorie declarations on drive-through menu boards and menus and menu boards located inside establishments. Another comment suggested that we emphasize that any list or display of a standard menu item that is primary to the consumer placing an order would constitute a menu or menu board.

One comment considered that a single store that has multiple menus or menu boards should be able to select the menu on which the calories must be disclosed. For example, a single store might have more than one menu board—with one such board being handwritten and highlighting specific special options. As long as every food offered for sale in the establishment is listed on one menu board and that menu board includes the necessary information, the comment considered that requiring calories on that one menu board should be sufficient. Alternatively, the comment suggested that the calorie declaration be required on the ''menu board of prominence,'' which the comment considered to be the menu board from which the order is placed.

Another comment similarly asserted that covered establishments must post the required information on the menu used most often rather than on all menus. Alternatively, the comment suggested that we provide an exemption for menus not commonly used by customers. In support of its suggestion, the comment pointed out that the statute uses the singular term ''writing'' and not a plural term. The comment stated that 90 percent of pizza customers order over the phone or the Internet or may order from memory. The comment asserted that to require nutrient information on every menu, menu board, Internet menu, or other writing is expensive, time consuming, and burdensome. The comment stated that it already uses in-store brochures to provide nutrition information to the small percentage of in-store customers. Although each franchisee in the applicable chain is required to carry certain menu items, the comment considered that each franchisee has the latitude to add items to the menu. Because the franchisee can add menu items to its menu, the comment asserted that it would be costly to a franchisee to change menu boards, because the franchisee will be required to order new menu boards and request calorie information for the new menu items.

One comment referred to an ''industry proposal'' for posting calories only on menus and menu boards that have the highest percentage of sales for that particular establishment, *e.g.,* Web sites used for Internet ordering and paper menus for phone ordering. This comment was opposed to any such proposal. The comment asserted that this approach would be an unfair business advantage for certain restaurants because it would allow some restaurants to provide calorie declarations on less expensive menus such as paper take-out menus or Internet Web sites while others would have to provide calorie declarations for more expensive in-restaurant menus and menu boards. The comment also expressed concern that any requirement for a covered establishment to declare calories on only the menus that listed substantially all menu items would exclude children's menus and dessert menus.

(Response 40) We agree with the comments in support of the proposed definition. We disagree that the required information should only be posted on the menu or menu board most often used by consumers in a covered establishment, the ''menu board of prominence,'' or only on the menus and menu boards that have the highest percentage of sales for a particular covered establishment. The critical factor is whether written material is or is part of the primary writing of a covered establishment from which a customer makes an order selection. It is not a matter of physical prominence of a menu, or the proportion of customers who order from a menu. Some consumers may want to select from a subset of standard menu items sold in the covered establishment. For example, if a consumer wanted to order only a dessert, he or she may ask for a dessert menu. As raised by one comment, if calorie information is listed only on the dinner menu, the consumer would not have access to the calorie information for the desserts if he or she is ordering from the dessert menu. As we stated in the proposed rule, given the importance for all consumers to have access to nutrition information when making order selections, we believe that the term ''primary writing'' should be interpreted from a consumer's vantage point (76 FR 19192 at 19202).

In addition, in the proposed rule, we tentatively concluded that a ''menu'' or ''menu board'' includes any writing of the covered establishment that is the primary writing from which a consumer makes an order selection (76 FR 19192 at 19201). We affirm this conclusion. The ''primary writing'' of an establishment can include more than one form of written material, such as a paper menu, a delivery menu, and a menu board; the critical factor is whether the written material is or is part of the primary writing of a covered establishment from which a customer makes an order selection. Further, we clarify that determining whether a writing is or is part of the primary writing from which a consumer makes an order selection depends on a number of factors, including whether the writing, such as a paper menu, delivery menu, or sign, lists the name of a standard menu item (or an image depicting the standard menu item) and the price of the standard menu item, and whether the writing can be used by a consumer to make an order selection at the time the consumer is viewing the writing (*e.g.,* the writing is posted at the cash register in a covered establishment, or the writing lists the phone number or email address of a covered establishment for purposes of placing an order).

Accordingly, a writing of a covered establishment that contains the name (or image) and price of a standard menu item, and that can be used by a consumer to make an order selection from the establishment at the time the consumer is viewing the writing would be a menu or menu board regardless of whether, for example, the writing is not the menu used most often by consumers. Another writing, such as a poster on a storefront, a banner or billboard located along a road or highway, or a tray-liner or table-tent at a quick-service restaurant, could be considered a ''secondary'' writing within this context and would not meet the definition of a ''menu or menu board,'' provided that such writing does not contain the name (or image) and price of a standard menu item, and cannot be used by a consumer to make an order selection at the time the consumer is viewing the writing.

We interpret the comment asserting that section 403(q)(5)(H)(xi) of the FD&C Act uses the singular term ''writing'' in defining the term ''menu or menu board'' as raising the question of what Congress intended ''primary writing'' to mean within the context of section 403(q)(5)(H)(xi) of the FD&C Act. In construing section 403(q)(5)(H)(xi) of the FD&C Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented (Chevron step one)? (*Chevron, U.S.A., Inc.* v. *NRDC, Inc.,* 467 U.S. 837, 842 (1984).) If the ''intent of Congress is clear,'' an Agency ''must give effect to the unambiguously expressed intent of Congress.'' (*Id.* at 843.) However, if ''Congress has not directly addressed the precise question at issue,'' and the statute is ''silent or ambiguous with respect to the specific issue,'' then our interpretation of the term ''primary writing'' will be upheld as long as it is based on a ''permissible construction of the statute (Chevron step two). (*Chevron,* 467 U.S. at 842–43; *FDA* v. *Brown & Williamson Tobacco Corp,* 529 U.S. 120, 132 (2000).) To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue. (See *e.g., Young* v. *Community Nutrition Institute,* 476 U.S. 974, 980 (1986).)

We have determined that, in enacting section 403(q)(5)(H)(xi) of the FD&C Act, Congress did not speak directly and precisely to the meaning of ''primary writing'' within the definition of ''menu or menu board.'' In conducting the Chevron step one analysis, we began with the language of section 403(q)(5)(H)(xi) of the FD&C Act. (See *e.g., Touche Ross & Co.* v. *Redington,* 442 U.S. 560, 568 (''[A]s with any case involving the interpretation of a statute, our analysis must begin with the language of the statute itself.'').) The term ''primary writing'' is not defined in section 403(q)(5)(H) of the FD&C Act or elsewhere in the FD&C Act. In general, a term that is undefined in a statute carries its ordinary meaning. (See *e.g., Perrin* v. *United States,* 444 U.S. 37, 42 (1979) (''A fundamental canon of statutory construction is that, unless otherwise defined, words will be interpreted as taking their ordinary contemporary, common meaning.'').) One common definition of the term ''writing'' is ''something written, especially (a) meaningful letters or characters that constitute readable matter . . . (b) a written work, especially a literary composition'' (Ref. 20). Similarly, another common definition of the term ''writing'' is ''something written: As (a) letters or characters that serve as visible signs of ideas, words, or symbols; (b) a letter, note, or notice used to communicate or record; (c) a written composition.'' (Ref. 21; see also Ref. 22).

One common definition of the term ''primary'' is ''first or highest in rank or importance; principal'' (Ref. 23; see also Refs. 24 and 25). Another common definition of the term ''primary'' is ''functioning or transmitting without intermediary: Direct'' (Ref. 25; see also Ref. 24).

Where, as here, the statutory language on its face does not clearly establish Congressional intent, it is appropriate to also consider other traditional tools of statutory construction, including other language in the section, the language, design, and purpose of the statute as whole, and legislative history. (See *e.g., Pharmaceutical Research & Manufacturers of America* v. *Thompson,* 251 F.3d 219, 224 (D.C. Cir. 2001); *Davis* v. *Michigan Department of Treasury,* 489 U.S. 803, 809 (1989); *Martini* v. *Federal National Mortgage Association,* 178 F.3d 1336, 1345 (D.C. Cir. 1999).) The other language in section 403(q)(5)(H)(xi) of the FD&C Act indicates that the writing at issue is writing of the establishment ''from which a consumer makes an order selection.'' Further, other provisions within section 403(q)(5)(H) of the FD&C Act indicate that requirements apply to more than one form of writing within a covered establishment. (See sections 403(q)(5)(H)(ii)(I) and (II) of the FD&C Act.) In addition, a general purpose of section 4205 of the ACA is to make calorie and other nutrition information available to consumers in a direct and

accessible manner to enable consumers to make informed and healthful dietary choices. Lastly, the legislative history does not suggest that Congress intended to limit the term to only one writing of the establishment.

Having determined that the meaning of ''primary writing'' in section 403(q)(5)(H)(xi) of the FD&C Act is ambiguous, we have determined that the final rule's interpretation of ''primary writing'' is a permissible construction of the statute (Chevron step two). In conducting the Chevron step two analysis, the same tools of statutory construction are available as those for the step one analysis.

First, the interpretation in the final rule is consistent with the plain meaning of the statute (Ref. 26). (See also *Perrin* v. *United States,* 444 U.S. 37, 42 (1979).) Under the final rule, a ''primary writing'' is ''something written,'' such as letters or characters on a sign or board. Further, determining whether the ''writing'' is ''primary,'' meaning of the most relevance or importance within this context or functioning without intermediary, or direct, depends on a number of factors, including whether the writing lists the name of a standard menu item (or an image depicting the standard menu item) and the price of the standard menu item, and whether the writing can be used by a consumer to make an order selection at the time the consumer is viewing the writing. In developing these factors, we considered other language in section 403(q)(5)(H)(xi) of the FD&C Act, specifically that the writing of the establishment is one ''from which a consumer makes an order selection.'' We also considered other language within section 403(q)(5)(H) of the FD&C Act, including sections 403(q)(5)(H)(i) and (ii)(I) and (II) of the FD&C Act, which together require a covered establishment to post calorie and other information on a menu and menu board. Further, in considering the general purpose of the section 4205 of the ACA, we determined that construing the term ''primary writing'' within the meaning of section 403(q)(5)(H)(xi) of the FD&C Act so as to include more than one form of writing, dependent on specific factors, would better serve the purposes of section 4205.

For all of these reasons, § 101.11(a) continues to specify that a menu or menu board is defined as the primary writing of the restaurant or similar retail food establishment from which a consumer makes an order selection.

In response to the comment regarding costs related to adding new menu items to a menu or menu board, we first note that section 403(q)(5)(H)(ii) of the FD&C Act requires covered establishments to declare calories on menus and menu boards for standard menu items listed on such menu and menu boards. Therefore, to the extent a covered establishment adds a new standard menu item to the establishment's menu or menu board, the establishment would be required to declare calories on the menu or menu board for the new standard menu item. Further, a covered establishment that decides to add a new menu item to a menu or menu board has already decided to incur the cost of redesigning or replacing the menu or menu board for such change—*i.e.,* to display the new standard menu item. In this situation, the additional cost to the establishment is the cost for determining the calorie information that must be declared for the new standard menu item.

Regarding costs related to determining nutrition information for standard menu items, we note that this rule also provides flexibility in order to minimize such costs. As discussed in section XVIII, section 403(q)(5)(H)(iv) of the FD&C Act provides that a restaurant or similar retail food establishment must have a reasonable basis for its nutrient content disclosures. As also discussed in section XVIII, this rule provides that a covered establishment can satisfy the requirements of 403(q)(5)(H)(iv) of the FD&C Act by various means, including use of nutrient databases, cookbooks, laboratory methods, and other reasonable means, including the use of Nutrition Facts on labels on packaged foods that comply with the nutrition labeling requirements of section 403(q)(1) of the FD&C Act and § 101.9, FDA nutrient values for raw fruits and vegetables in Appendix C of part 101 (21 CFR part 101), or FDA nutrient values for cooked fish in Appendix D of part 101 (see § 101.11(c)(1)). In addition, this rule provides that a covered establishment can satisfy the requirements of 403(q)(5)(H)(iv) of the FD&C Act by relying on nutrition information for a standard menu item determined by the establishment's corporate headquarters or parent entity (see § 101.11(c)(3)(i)(F), (c)(3)(iii)(D), and (c)(3)(iv)(D)). In some cases, a corporate headquarters or parent entity could decide to maintain a nutrient database and use it to determine nutrition information for specialty standard menu items offered for sale by one or a few individual establishments in the chain. Therefore, this rule provides flexibility for covered establishments in order to minimize costs while also helping to ensure that calorie and other nutrition information is made available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices.

(Comment 41) A few comments appeared to believe that the proposed rule would require covered establishments to post or otherwise have menu boards for disclosing calorie information. These comments asked for other options for disclosing calories. One comment suggested that large menu boards should not be required because they will obscure the consumers' view of the preparation of their food and thereby create a food safety issue. One comment suggested that we consider ''technological solutions'' instead of menu boards, *e.g.,* use of a kiosk near the point of sale. The comment also suggested that we provide flexibility to cover alternative sources such as a daily feature board.

One comment asked us to provide flexibility for facilities that operate in locations too small to display a menu board by allowing establishments to choose among several different options for display methods. As one alternative to the traditional menu board, the comment asked us to permit the use of a display terminal to provide nutrition information for menu items or allow ''menu identifiers'' (a term the comment did not define) at the point of selection, and to permit nutrition information to be displayed adjacent to the food item in cafeteria and buffet type settings.

(Response 41) Some comments may have misinterpreted the proposed rule. We did not propose to require that covered establishments post or otherwise have menu boards. Rather, within this context, we proposed to define the terms ''menu'' and ''menu board,'' based on the statutory definition at section 403(q)(5)(H)(xi) of the FD&C Act, and to provide direction regarding what information must be disclosed on menus and menu boards for covered establishments that have menus and menu boards. That proposed definition relies on the concept of a primary writing. If an electronic display is the primary writing of the covered establishment from which a customer makes an order selection, it would satisfy our definition of a menu or menu board. As such, electronic menus may be used by covered establishments, and we have retained electronic menus as an example of menus in the definition of menu or menu board in § 101.11(a).

Standard menu items offered for sale in covered establishments with cafeteria- and buffet-type settings are most likely foods on display or self-service foods. As discussed in section XVII.B, for a food on display or a self-

service food, section 403(q)(5)(H)(iii) of the FD&C Act and § 101.11(b)(2)(iii) require covered establishments to place a sign adjacent to the food listing calories per displayed food item or per serving. This rule provides flexibility for covered establishments by providing a number of options for meeting the requirements of section 403(q)(5)(H)(iii) of the FD&C Act and § 101.11(b)(2)(iii). For example, covered establishments are permitted to declare calories for a food on display or a self-service food by posting calorie declarations on signs adjacent to the food, on a sign attached to a sneeze guard, or on a single sign or placard (§ 101.11(b)(2)(iii)(A)). Therefore, this rule provides flexibility, as requested by some comments, for covered establishments to choose among several options for declaring calorie information for standard menu items, including self-service foods or foods on display in cafeteria and buffet-type settings.

(Comment 42) In the proposed rule, we noted that many consumers order restaurant-type food from restaurants or similar retail food establishments over the phone or Internet. We tentatively concluded that if consumers can order from a covered establishment online, over the phone, or by fax, using a writing of the covered establishment on the Internet as the primary writing from which he or she makes his or her order selection, then the writing on the Internet is a menu for the purposes of section 403(q)(5)(H) of the FD&C Act (76 FR 19192 at 19202). Some comments asked us to keep in mind the need to keep up with technology and not have a rigid standard.

(Response 42) The definition of ''menu or menu board'' clearly specifies that menus may be in different forms and does not establish a standard for the technology used on a menu or menu board. The definition lists a number of examples of primary writings that may be menus or menu boards, including electronic menus and menus on the Internet, that are not meant to be all-inclusive, as indicated by use of the terms ''including, but not limited to'' before the examples. Because a menu or menu board is defined as the primary writing of the covered establishment from which a customer makes an order selection, the definition is adequate to capture methods and media other than those specifically listed in that definition, so long as such methods and media otherwise satisfy the criteria in the definition.

(Comment 43) Several comments noted that some local zoning laws do not permit restaurants with drive-through windows to build larger menu boards. These comments expressed concern about how to comply with the new requirements for menu boards in light of State or local size restrictions. One comment asked us to provide more flexibility for compliance, including permitting the use of a pamphlet next to the drive-through menu board. Some comments suggested that we allow nutrition information on a large poster adjacent to the menu board.

A few comments supported the use of stanchions (*i.e.,* free-standing boards that are not connected to the menu board and are often placed near drive-through menu boards) to post calorie information. One comment maintained that restaurants and similar retail food establishments have a vested interest in customer satisfaction in the context of drive-through windows and have concluded that clear and organized space, presented within the framework of a known brand, is the most critical success factor in presenting information to consumers on menu boards. This comment considered that stanchions adjacent or close to menu boards are ''complete thoughts'' if the information is relevant, well organized, and clearly marked, and that such stanchions will help consumers with their menu choices. The comment considered that in many cases information on stanchions is more clear and conspicuous than on menu boards. The comment noted that calorie information is provided on stanchions in some jurisdictions that require nutrition labeling on menus and menu boards, including Montgomery County (Maryland), New York City, Philadelphia, and certain counties in New York. The comment maintained that the current use of stanchions in some jurisdictions is evidence of its effectiveness, and noted that some States and localities permit stanchions because information is hard to read on already crowded drive-through menu boards.

A comment from a quick-service restaurant chain asserted that stanchions are less costly to update and replace than menu boards. The chain had conducted a consumer survey of customers who purchased food from the chain's drive-through windows in 13 of the chain's restaurants that use stanchions, as permitted in King County, Washington, and submitted a report of this survey to the docket for this rule (Ref. 27). For the 128 customers surveyed, the comment reported that 92 percent felt it was easy to find calories, 98 percent felt calories were easy to understand, 95 percent thought the stanchion location was clearly visible to consumers, 95 percent noted nothing blocked view of stanchion, and 76 percent felt they had adequate time to review before ordering.

One comment considered that while ''the statute'' refers to menus and menu boards, it also gives us authority to define those terms. (We assume this comment is referring to section 4205 of the ACA.) The comment stated that we could include stanchions as a method to communicate calorie information that is clear and conspicuous.

Several comments agreed with our tentative conclusion that stanchions inadequately convey calorie information. The comments asserted that it is challenging for consumers to read different information in different locations at a drive-through window especially when trying to read the information from a car, where consumers have limited mobility and a limited field of vision. The comments also asserted that, even with different zoning laws, drive-through menu boards have enough room for calories, although photos and other marketing information may need altering. One comment pointed out that separate stanchions would not comply with section 403(q)(5)(H)(ii) of the FD&C Act, which requires that calories be on the menu board itself.

(Response 43) We disagree that the rule should provide for declaration of calorie information in pamphlets or on posters or stanchions, rather than on the menu board at a drive-through in a covered establishment. In the proposed rule, we tentatively concluded that stanchions inadequately convey calorie information because a situation in which customers need to look to one board (the menu board) for important food-selection information, such as price, and another (the stanchion) for calories, is likely to be more difficult for customers attempting to use the declared calorie information at the point of selection (76 FR 19192 at 19206). We also tentatively concluded that this is particularly true in the drive-through context, where customers have a restricted field of vision from their car windows, and may have a relatively short time to consider the menu board prior to ordering, because customers often cannot view the full menu while waiting in line. As discussed further in the following paragraphs, the comments provide insufficient basis for us to conclude otherwise, and as a result, we affirm our conclusion from the proposed rule.

In addition, section 403(q)(5)(H)(ii)(II)(aa) of the FD&C Act requires the number of calories contained in standard menu items to be disclosed on the menu board itself.

Section 403(q)(5)(H)(xi) of the FD&C Act defines ''menu'' or ''menu board'' as ''the primary writing of the restaurant or similar retail food establishment from which a customer makes an order selection.'' Because a stanchion is a free-standing board that is not connected to a drive-through menu board and therefore typically is not used by consumers to make order selections, we do not consider it to meet the definition of ''menu'' or ''menu board'' as defined in this rule and section 403(q)(5)(H)(xi) of the FD&C Act. Accordingly, we concluded that a stanchion cannot be the means by which a covered establishment discloses calorie declarations on menus and menu boards as required under section 403(q)(5)(H)(ii) of the FD&C Act and this rule.

We considered the consumer survey results provided with one comment and did not find the information adequate to overcome the concerns we raised in the proposed rule regarding the use of stanchions (Ref. 28). Although the participants expressed favorable impressions of the stanchions, the survey data:

- Did not provide a comparison with other calorie displays, including calorie declarations on drive-through menu boards without stanchions;
- Did not show whether participants would have more or less favorable impressions of calorie declarations on drive-through menu boards without stanchions.
- Only showed that the participants liked the display and not whether the display was useful for them in making their order selections; and
- Did not assess the use of stanchions in situations where the consumer needs to make quick decisions because other consumers are in the drive-through line behind them.

For all of the reasons discussed in response to this comment, this rule does not provide for declaration of calories in a pamphlet or on a stanchion at a drive-through of a covered establishment as a means of satisfying the requirement that the number of calories contained in a standard menu item be disclosed on the menu and the menu board, as required by section 403(q)(5)(H)(ii) of the FD&C Act and § 101.11(b)(2)(i).

(Comment 44) Some comments asserted that the proposed rule allows the Secretary to amend the nutrition information that must be disclosed and that this will further burden restaurants to replace drive-through and interior menu boards multiple times.

(Response 44) We interpret the comments as referring to section 403(q)(5)(H)(vi) of the FD&C Act. Under section 403(q)(5)(H)(vi) of the FD&C Act, the Secretary (and, by delegation, FDA) may, by regulation, require the disclosure of a nutrient, other than a nutrient required under section 403(q)(5)(H)(ii)(III) of the FD&C Act, in the written nutrition information that is available to consumers upon request if FDA determines that the nutrient information should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices. If this is indeed what the comments mean, the comments appear to have confused section 403(q)(5)(H)(vi) of the FD&C Act with the requirements in section 403(q)(5)(H)(ii)(I)(aa) related to the disclosure of calories on a menu or menu board. The statutory authority in section 403(q)(5)(H)(vi) of the FD&C Act for FDA to require disclosure in the written nutrition information of a nutrient other than one required under section 403(q)(5)(H)(ii)(III) of the FD&C Act does not address the calories declarations that must be on a menu or menu board.

(Comment 45) In the proposed rule, we stated that we recognize that some establishments may send menus as a form of advertising. We tentatively concluded that advertisements for food fall outside the scope of section 4205 of the ACA. However, take-out and delivery menus, which include all or a significant portion of items offered for sale and serve as the primary writing from which consumers make their order selections, would be menus under the proposed rule (76 FR 19192 at 19201).

Several comments considered that the proposal did not adequately distinguish between menus and menu boards and advertisements or promotional material. One comment considered that it is not appropriate to require calorie disclosure in advertising, such as a postcard announcing a new restaurant that has pictures of a few sample dishes. However, the comment also considered that when the advertising is the menu itself and can be used as the ''primary writing'' a customer uses to make an order, calorie disclosure should be required. The comment recommended that the test be whether customers can use the menu as a primary writing for making their selection, not the way in which the menu is presented or delivered to the customers by the restaurant or similar retail food establishment. One comment asked us to clarify that calorie disclosure should be on any menu regardless of whether the menu also serves as a marketing tool. One comment stated that any list of covered food items that is the primary vehicle from which a customer places his or her order constitutes a menu. The comment noted that in some instances, an in-store sign that looks like an advertisement (*e.g.,* promotional poster) for a menu item is the primary vehicle from which the customer orders the menu item when the menu item is not included on the menu but is included only on that sign. This comment asked us to make clear that a sign listing a menu item that is only listed on that sign makes it a menu board.

One comment asked us to make clear that covered menus include individualized order sheets used at certain restaurants. Another comment asked us to make clear that take-out menus are included and suggested that a take-out menu be added as an example to the definition in the regulation.

Some comments asked us to make a clear statement that advertisements and promotional material such as table top stands, newspaper advertisements and flyers, tray liners and point of purchase marketing materials are not menus, even if they list some names and prices. One comment noted that, in the proposed rule, we tentatively concluded that ''advertisements for food fall outside the scope of section 4205'' but did not include this statement in the proposed definition. The comment asserted that we hinted at potential grounds for excluding some menus from coverage, when we stated that ''take-out and delivery menus, *which include all or a significant portion of items offered for sale* and serve as the primary writing from which consumers make their order selections, would be menus under the proposed rule'' (76 FR 19192 at 19202; emphasis added by comment). The comment expressed concern that, without specific language in the final regulation that advertisements are not menus and thus fall outside the scope of section 4205 of the ACA, the terms ''menu'' or ''menu board'' could be construed to encompass materials that list menu items but that are in fact used as advertisements. The comment maintained that this clarity is needed to ensure consistent enforcement. The comment also recommended that we expand on our statement that such promotional materials are menus subject to the menu labeling requirements if they ''include all or a significant portion of items offered for sale.'' The comment asserted that limiting labeling requirements, for example, to only menus listing more than a certain percentage of standard menu items sold by the restaurant would have the practical effect of limiting the number of pieces covered, excluding many promotional items (such as door hangers and pizza box tops) and creating an

objective standard that could guide both restaurant behavior and enforcement. The comment considered that requiring calorie disclosures on promotional material is especially burdensome for some of the franchises who pay for this promotional material.

One comment stated that circular advertisements should not be menus. Another comment recommended that grocery store signs that highlight the attributes of a food in the store not be considered a menu or menu board. One comment supported including nutrition information on any food advertisement that makes a health claim.

(Response 45) As discussed previously in this document, the term ''menu'' or ''menu board'' includes any writing of the covered establishment that is the primary writing from which a consumer makes an order selection. As discussed in Response 40, determining whether a writing is or is part of the primary writing from which a consumer makes an order selection depends on a number of factors, including whether the writing, such as a take-out menu, sign, or poster, lists the name of a standard menu item (or an image depicting the standard menu item) and the price of the standard menu item, and whether the writing can be used by a consumer to make an order selection at the time the consumer is viewing the writing (*e.g.,* the writing is posted at the cash register in a covered establishment, or the writing lists the phone number or email address of a covered establishment for purposes of placing an order). Accordingly, a writing of a covered establishment that contains the name (or image) and price of a standard menu item, and that can be used by a consumer to make an order selection from the establishment at the time the consumer is viewing the writing would be a menu or menu board regardless of whether, for example, the writing is mailed to a consumer's home or is posted inside a covered establishment. In contrast, written material of an establishment that does not satisfy this criteria, such as a poster on a storefront, a coupon or other promotional material, banners, tray liners, billboards, and stanchions, could be considered a ''secondary writing'' of an establishment.

We recognize that, in the proposed rule, we tentatively concluded that take-out and delivery menus would be considered menus within the meaning of section 403(q)(5)(H)(xi) of the FD&C Act to the extent that such menus include all or a significant portion of items offered for sale (76 FR 19192 at 19201). However, we are not affirming this conclusion for a number of reasons. First, we agree with the comment asserting that the critical factor should be whether the take-out or delivery menu is or is part of the primary writing from which a consumer makes an order selection, not the way in which the menu is presented or delivered to consumers.

Second, as discussed previously in this document, in this rule we clarified the factors to be considered in determining whether a writing is or is part of the primary writing from which a consumer makes an order selection, and these factors help clarify whether a writing constitutes a menu or menu board or an advertisement or promotional material, as requested by several comments. Further, in light of these factors, if we were to conclude that delivery or take-out menus would only be considered menus if they included all or a significant portion of items offered for sale, that conclusion would be inconsistent with how we will be determining whether other written material constitutes a primary writing of an establishment from which a consumer makes an order selection, particularly since consumers can use take-out and delivery menus to make order selections in generally the same way as they would use dine-in menus.

In addition, menus vary in size and selection. A covered establishment that has a single menu for daily use, including menu offerings for breakfast, lunch, and dinner, may nonetheless have separate take-out menus directed only to breakfast, lunch, or dinner. We see no reason to treat a take-out menu that only includes menu offering for breakfast any differently than we would treat a breakfast menu used by consumers to order and consume breakfast while seated at the establishment.

For these reasons, in this rule we are not affirming the proposed rule's tentative conclusion that take-out and delivery menus would be considered menus within the meaning of section 403(q)(5)(H)(xi) of the FD&C Act to the extent that such menus include all or a significant portion of items offered for sale. Instead, in this document we identify factors we would use to determine whether a writing is the primary writing from which a consumer makes an order selection—*i.e.,* the name (or image) and price of the standard menu item food and a means to make an order selection at the time the consumer is viewing the writing. Accordingly, determining whether a writing is a menu or menu board does not depend on how many items are listed. If a writing constitutes a menu or menu board within the meaning of section 403(q)(5)(H)(xi) of the FD&C Act and § 101.11(a), it must contain the information required under section 403(q)(5)(H) of the FD&C Act and § 101.11(b), regardless of the number of items on that menu or menu board.

Any written material that is or is part of the primary writing from which a consumer makes an order selection, whether it is an individualized order sheet or a take-out menu, would be a menu for purposes of this rule if it includes the name (or image) and price of a standard menu item and a means by which a consumer can make an order selection from the establishment at the time the consumer is viewing the writing. Providing calorie and other required information on menus and menu boards will make such information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices.

Using these factors, other writings of a covered establishment, such as newspaper ads, circular advertisements, banners, or postcards that announce a new restaurant and provide pictures of sample dishes generally would not be menus or menu boards. Although it is possible that such writings could include the name (or image) and price of standard menu items, they generally would not provide a means by which a consumer can make an order selection at the time the consumer is viewing the writing and therefore such a writing would not constitute a primary writing from which a consumer makes an order selection within the meaning of section 403(q)(5)(H)(xi) of the FD&C Act. Likewise, a sign in a grocery store that highlights attributes of a standard menu item (*e.g.,* by the name or image of the menu item), without including the price, would not be a menu or menu board.

While a writing may constitute a menu or menu board, not all of the menu items listed on such writing would require calorie declarations. For example, if the requirements of section 4205 of the ACA do not apply to a food (*e.g.,* as a daily special, temporary menu item, or customary market test item), a covered establishment would not be required to declare calories or other nutrition information for such food under this rule, meaning that a writing listing a daily special or temporary menu item would not be required to bear a calorie declaration for such item. Further, as discussed later in this document (see Response 79), for certain ''mix and match'' situations, where the menu or menu board describes an opportunity for a consumer to combine standard menu items for a special price

(*e.g.,* ''Combine Any Sandwich with Any Soup or Any Salad for $8.99''), and the calories for each standard menu item, including each size option if applicable, available for the consumer to combine are declared elsewhere on the menu or menu board, a covered establishment would not be required to declare the calories for such item (see § 101.11(b)(2)(i)(A)(*6*)(*iv*)).

The comment supporting nutrition information on any food advertisement that makes a health claim is outside the scope of this rule, which establishes requirements for declaring nutrition information for standard menu items offered for sale in establishments covered by the requirements of section 4205 of the ACA. We note, however, that material that constitutes food labeling within the meaning of section 201(m) of the FD&C Act would be subject to the requirements in § 101.10. Under section 201(m) of the FD&C Act, the term ''labeling'' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(Comment 46) One comment recommended that menu labeling requirements apply to airline magazines that include menus.

(Response 46) In the proposed rule, we tentatively concluded that most airplanes would not satisfy the definition of ''restaurant or similar retail food establishment'' because, in general, they do not present themselves to the public as restaurants, nor are they likely to meet the floor space (or revenue) threshold. As discussed in section VI.D, under the definition of ''covered establishment'' established in this rule airplanes are not covered establishments that must comply with the rule. Therefore, the nutrition labeling requirements of this rule do not apply to airline magazines that include menus.

VIII. Comments and FDA Response on the Proposed Definition of Terms Related to Foods Covered by the Rule (Proposed § 101.11(a))

A. Restaurant Food and Restaurant-Type Food

As discussed in section VI.C, after considering comments, we are deleting the proposed definition of ''restaurant food'' and establishing a revised definition of ''restaurant-type food'' that better reflects the food most like the food offered for sale in restaurants. We discussed these changes to two terms related to foods covered by the rule within section VI because the definition of ''restaurant-type food'' established in this rule is one of several terms related to the scope of establishments covered by the rule.

B. Standard Menu Item

Proposed § 101.11(a) would define ''standard menu item'' as a restaurant or restaurant-type food that is routinely included on a menu or menu board or routinely offered as a self-service food or food on display. In the following paragraphs, we discuss comments on this proposed definition. We are finalizing it without change, except to revise ''restaurant or restaurant-type food'' to ''restaurant-type food'' to conform with our deletion of the term ''restaurant food'' throughout the rule (see section VI.C).

(Comment 47) Several comments supported the proposed definition. One comment opposed the proposed definition because it is ''incomplete'' and misunderstands the meaning of ''standard'' within the context of a chain of 20 or more restaurants and similar retail food establishments doing business under the same name and offering for sale substantially the same menu items. The comment argued that it is not the regularity with which a menu item is sold at a given restaurant that renders the item ''standard'' within the context of a restaurant chain; rather, it is the fact that the menu item is offered across many establishments in the chain, in substantially the same form, and is prepared according to the same recipe and using the same ingredients. The comment maintained that when foods are standardized, nutrition information can be derived. On the other hand, according to the comment, if foods do not have a common recipe, nutrition information would be determined case-by-case, which is impractical and cost prohibitive. The comment suggested the following definition: ''A menu item that appears on the menus of substantially all restaurants in a chain that uses the same general recipe and that is prepared in substantially the same way with substantially the same food components, even if the name of the menu item varies.''

The comment also recommended that, for a chain that prints a single standardized menu for all its restaurants or establishments or for those in a given region, the term ''standard menu item'' be interpreted to refer to menu items that appear on those centrally printed and distributed menus. The comment maintained that adopting this definition would harmonize the terms ''standard menu item'' and ''covered establishment'' and ensure that the requirements apply to the foods that are subject to the type of standardization that would allow them to be consistently prepared. The comment also requested that a covered establishment be allowed but not required to provide the nutrition information in writing at the point of sale for menu items offered for sale in only some establishments in a chain if we decide to include such menu items within the definition of standard menu item in the final rule. Otherwise, the comment considered that a chain retail food establishment would have to include, in nutrition brochures, information on many menu items that are sold in a small percentage of stores, which could be confusing and costly.

(Response 47) We disagree that the definition of ''standard menu item'' should be based on whether the menu item is offered across substantially all of the establishments within the chain, in substantially the same form, and is prepared according to the same recipe and using the same ingredients. Section 403(q)(5)(H)(i) of the FD&C Act provides, in relevant part, that ''in the case of food that is a standard menu item that is offered for sale in a restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name . . . and offering for sale substantially the same menu items, the restaurant or similar retail food establishment shall disclose the [required] information. . . .''. The statutory language does not indicate that a menu item must be offered for sale in all of the restaurants or similar retail food establishments within a chain in order for it to be a ''standard menu item'' at a particular covered establishment. Indeed, it would be burdensome and impractical for establishments and inspectors to continually evaluate all of the menu items offered by a chain to determine which items are offered by all establishments in the chain in order to determine whether a given menu item is a standard menu item subject to requirements of this rule. In addition, we have no evidence that it would be impractical and cost prohibitive to require covered establishment to provide the nutrition required by this rule for menu items that they routinely offer. We continue to believe that it is reasonable to interpret ''standard menu item'' to mean a restaurant-type food routinely included on a menu or menu board or routinely offered as a self-service food or food on display in a given covered establishment.

We would not object to central printing of a single, standardized menu for use by all covered establishments within a chain, provided that the

centrally printed menu complies with the requirements of this rule and applicable provisions of the FD&C Act. However, if an individual covered establishment offers for sale an additional standard menu item that is not offered by every establishment in the chain and, therefore, is not included on the centrally printed menu, that establishment still must comply with all applicable requirements of this rule for that standard menu item, including where and how the nutrition information must be disclosed.

We disagree that a covered establishment would have to include, in nutrition brochures, information on many menu items that are sold in a small percentage of stores. A covered establishment need only provide the required information for the standard menu items it offers for sale.

(Comment 48) A few comments stated that grocery stores use items from other departments within the grocery store (*e.g.,* meat department, produce department) to make its prepared food items. The ingredients for a given prepared food can vary significantly depending on the availability of items in the store. These comments argued that labeling and determining calorie information for these items would be difficult.

(Response 48) If a prepared food item varies significantly depending on what ingredients a covered establishment happens to have available, the item may not meet the definition of standard menu item. For example, if a grocery store with a hot soup bar offers a different vegetable soup every day based on whatever vegetables the store happens to have in surplus (*e.g.,* cabbage and tomatoes soup one day, carrots and leeks the next, spinach and squash on a third day), and if none of these vegetable soups is offered for sale routinely, then none of the vegetable soups would meet the definition of standard menu item. Even if the grocery store names each version of the soup as ''vegetable soup,'' the item would not be considered a standard menu item, because the soup's ingredients significantly differ daily.

C. Combination Meal

Proposed § 101.11(a) would define ''combination meal'' as a standard menu item that consists of more than one food item, for example a meal that includes a sandwich, a side dish, and a drink. The proposed definition would further provide that a combination meal may be represented on the menu or menu board in narrative form, numerically, or pictorially. Some combination meals may include a variable menu item (or be a variable menu item as defined in § 101.11(a)) where the components may vary. For example, the side dish may vary among several options (*e.g.,* fries, salad, or onion rings) or the drinks may vary (*e.g.,* soft drinks, milk, or juice) and the customer selects which of these items will be included in the meal.

Comments that addressed the proposed definition agreed with it. Therefore, we are finalizing it without change, except to correct a typographical error by removing an open parenthesis mark between ''may include a variable menu item'' and ''or be a variable menu item . . .''

D. Variable Menu Item

Proposed § 101.11(a) would define ''variable menu item'' as a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item. In the following paragraphs, we discuss comments on this proposed definition. We are finalizing it without change.

(Comment 49) Several comments considered that the term ''variable menu item'' does not include items listed on a menu that can be assembled in varying combinations, such as pizza. These comments suggested that the definition of variable menu item be revised to ''a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item. It does not include foods, beverages, or meals that are listed as separate menu items but could be combined in a variety of combinations or that are different sizes of the same menu item.''

Several comments asked that we clarify that the definition for ''variable menu item'' does not mean different sizes. They maintained that each size should be accompanied by a calorie declaration. In contrast, one comment opposed the posting of calories for different sizes, maintaining that providing calorie information for each size would take too much space and might force the reduction in font size. This comment asked us to permit covered establishments to provide a range of calories to reflect the calorie content range from the smallest to the largest size for beverages offered as standard menu items. This comment considered that the statute provides us discretion to allow covered establishments to provide calorie information for different sized beverages using ranges, as long as the calorie information is clear and conspicuous.

(Response 49) We disagree that variable menu items do not include foods such as pizza. Our proposed definition is consistent with section 403(q)(5)(H)(v) of the FD&C Act, which expressly includes pizza as an example of a standard menu item that comes in different flavors, varieties, or combinations, but is listed as a single menu item. For example, a menu or menu board can list a pizza with a particular price and up to four toppings. This is an example of a food that comes in different varieties because the consumer has the choice of various toppings.

We agree with the comments asserting that different sizes of a standard menu item are not variable menu items, but disagree with the comment opposing the posting of calories for different sizes. Section 403(q)(5)(H)(v) of the FD&C Act provides, in relevant part, that FDA shall establish by regulation standards for disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as single menu items. When a standard menu item, including a beverage, is listed on a menu or menu board by name with different sizes, or each size has its own price, each size would constitute a standard menu item rather than a different flavor, variety, or combination, and each standard menu item must include a calorie declaration.

E. Food on Display

Proposed § 101.11(a) would define food on display as restaurant or restaurant-type food that is visible to the customer before the customer makes a selection, so long as there is not an ordinary expectation of further preparation by the consumer before consumption. In the following paragraphs, we discuss comments on this proposed definition. After considering comments, we are finalizing the definition without changes, except to revise ''restaurant or restaurant-type food'' to ''restaurant-type food'' to conform with our deletion of the term ''restaurant food'' throughout the rule (see section VI.C).

(Comment 50) A few comments agreed with the proposed definition. Other comments suggested modifications to the definition. Some comments recommended that the definition clarify that the food can be self-serve or served by the restaurant staff and that the food could be in the open or behind glass. The comments suggested that the following language be added to the proposed definition: ''It includes food that is served by restaurant staff or self-served by customers and foods with Nutrition Facts labels that customers cannot examine without assistance. Food on display can be behind glass or other

material or in an open display accessible to consumers.''

(Response 50) We decline the requests to revise the proposed definition. The definition applies regardless of whether the food is self-serve or served by the restaurant staff, whether it is in the open or behind glass, or whether it has a Nutrition Facts label that can be examined by a consumer without assistance. In addition, we do not want to appear to limit the definition to only those foods described in the language suggested by the comment.

(Comment 51) One comment asserted that food on display, such as deli meats and cheeses, should be covered even if there is an expectation that there will be further preparation before consuming. A few comments asked that we clarify that foods on display and self-service food do not include fresh breads, cheese wheels, bulk olives, bulk sauces, condiments, and salads sold by the pound like ''tuna salad, egg salad, chicken salad, etc.'' One comment recommended that grocery stores provide calories for bakery items, prepared deli foods such as salads and sandwiches, prepared meals and side dishes, freshly cooked pizza, fountain drinks, salad bars, and other foods sold for immediate consumption. One comment requested an exemption for certain food items prepared for home consumption, such as fruit slices, fruit cups, fruit salads, containers of fresh-cut fruit, fresh squeezed juices, bulk or packaged nuts, seeds, or dried fruit, and similar items that are packaged (or in the case of bulk products, are sold in containers that are available for self-packaging).

(Response 51) As discussed in section VI.C, we are establishing a revised definition of ''restaurant-type food'' that better reflects the food most like the food offered for sale in restaurants (see Comment 24 and Response 24). Because restaurants typically sell food that is fully prepared, deli meats and cheese generally will not meet the definition of ''restaurant-type food,'' and therefore generally will not be covered. However, certain foods offered for sale in grocery stores that are visible to the consumer before the consumer makes a selection, such as prepared sandwiches, freshly cooked pizza, and salad and hot food bars would meet the definition of restaurant type food and do not have an ordinary expectation of further preparation by the consumer before consumption. These foods meet the definition of foods on display. Other foods commonly offered for sale by grocery stores are not within the definition of ''restaurant-type food'' and would not be subject to the nutrition disclosure requirements of this rule (*e.g.,* foods such as dried fruit and nuts bought from bulk bins or cases; foods such as loaves of bread, bags or boxes of dinner rolls, whole cakes, bags or boxes of candy or cookies to be eaten over several eating occasions or stored for later use; foods such as deli salads sold by unit of weight that are not self-serve and are not intended solely for individual consumption, either prepacked or packed upon consumer request).

F. Self-Service Food

Proposed § 101.11(a) would define ''self-service food'' as restaurant or restaurant-type food that is available at a salad bar, buffet line, cafeteria line, or similar self-service facility and that is served by the customers themselves. Self-service food also includes self-service beverages. Comments that addressed the proposed definition supported it. We are finalizing it without changes, except to revise ''restaurant or restaurant-type food'' to ''restaurant-type food'' to conform with our deletion of the term ''restaurant food'' throughout the rule (see section VI.C).

G. Custom Order

Proposed § 101.11(a) would define ''custom order'' as a food order that is prepared in a specific manner based on an individual customer's request, which requires the restaurant or similar retail food establishment to deviate from its usual preparation of a menu item, *e.g.,* a club sandwich without the bacon if the establishment usually includes bacon in its club sandwich. In the following paragraphs, we discuss comments on this proposed definition. We are finalizing it without change, except for two clarifications. First, we are clarifying that the deviation is from the usual preparation of a *standard* menu item (emphasis added). Second, we are replacing the term ''restaurant or similar retail food establishment'' with ''covered establishment'' to clarify the applicability of the definition (see the discussion in section VI.I).

(Comment 52) Several comments agreed with the proposed definition. Some comments considered that the custom order exemption should apply to custom birthday cakes and sandwiches made to order, because they have no standard preparation from which to deviate.

One comment maintained that supermarkets often preprint labels or previously affix them to packaging (*e.g.,* a paper bag for a sandwich or bread) to improve efficiency or to save costs. Because consumers may request that toppings be added or removed from a food item that is sold in the prelabeled packaging, the comment considered that this would be a custom order that would be exempt from the menu labeling requirements. The comment asked us to clarify that the product would not be misbranded if the packaging contained nutrition information based on the standard preparation.

(Response 52) If a custom birthday cake that is made to order is not routinely included on a menu or menu board or routinely offered as a self-service food or food on display, it would not be covered by the rule, because it is not a standard menu item.

We agree that a sandwich that is made to order can be a custom order if the sandwich is prepared in a specific manner based on an individual customer's request, which requires the covered establishment to deviate from its usual preparation of a standard menu item. However, some sandwiches that are made to order can be variable menu items, depending on how the food is depicted on a menu or menu board or otherwise offered for sale. We discuss the definition of variable menu item in section VIII.D.

We also agree that if a customer asks that toppings be changed or removed from a standard menu item, and the standard menu item normally includes certain toppings, the customer's order is a custom order. In response to the question regarding the use of a preprinted label on a food product, which is subject to modification, we first note that a food order that is prepared in a specific manner based on an individual customer's request, which requires a covered establishment to deviate from its usual preparation of a standard menu item, is a custom order and is not subject to the requirements of section 403(q)(5)(H) of the FD&C Act and this rule. Nevertheless, food labeling, including nutrition labeling, for a food must be truthful and not misleading (section 403(a)(1) of the FD&C Act). If a label on a food bears nutrition information for such food that is false or is otherwise misleading, the food would be misbranded under section 403(a)(1) of the FD&C Act. Accordingly, if a custom order, such as a club sandwich without the bacon if the establishment usually includes bacon in its club sandwich, bears nutrition information in a preprinted label that is false or is otherwise misleading, such food could be misbranded under the FD&C Act. We recommend that covered establishments refrain from affixing preprinted labels on custom orders unless the information

included on such labels is truthful and not misleading.

H. Daily Special

Proposed § 101.11(a) would define ''daily special'' as a menu item that is prepared and offered for sale on a particular day, that is not routinely listed on a menu or offered by the covered establishment, and that is promoted by the covered establishment as a special menu item for that particular day.

Comments that addressed the proposed definition agreed with it. Therefore, we are finalizing it without change, except to add ''or menu board'' after ''not routinely listed on a menu.'' We inadvertently omitted ''or menu board'' in the proposed definition.

I. Food That Is Part of a Customary Market Test

Proposed § 101.11(a) would define ''food that is part of a customary market test'' as food that is marketed in a covered establishment for fewer than 90 consecutive days in order to test consumer acceptance of the product. Comments that addressed the proposed definition agreed with it. Therefore, we are finalizing it without change, except for changes to clarify that food that is part of a customary market test is food ''that appears on a menu or menu board for less than 90 consecutive days'' rather than food ''that is marketed in a covered establishment for fewer than 90 consecutive days.'' These changes are consistent with section 403(q)(5)(H)(vii)(I)(cc) of the FD&C Act, our description of ''food that is part of a customary market test'' in the proposed rule (76 FR 19192 at 19205), and with the definition for ''temporary menu item'' in § 101.11(a).

J. Temporary Menu Item

Proposed § 101.11(a) would define ''temporary menu item'' as a food that appears on a menu or menu board for less than a total of 60 days per calendar year. Proposed § 101.11(a) would explain that the 60 days includes the total of consecutive and non-consecutive days the item appears on the menu. In the following paragraphs, we discuss comments on this proposed definition. We are finalizing it without change.

(Comment 53) Several comments agreed with the proposed definition. One comment agreed that the 60 days need not be consecutive, but considered that seasonal items (such as the pumpkin-flavored latte example we included in the proposed rule (76 FR 19192 at 19205)) should not be exempt if they are routinely offered each year.

One comment recommended that we change the definition for temporary menu item to shorten the time period from 60 to 45 days, to discourage restaurants from continuously changing menus to avoid calorie disclosure.

(Response 53) The proposed definition for ''temporary menu item'' focused on the explicit statutory language in section 403(q)(5)(H)(vii) of the FD&C Act, which provides in relevant part that the requirements of section 403(q)(5)(H)(i) through (vi) of the FD&C Act do not apply to ''temporary menu items appearing on the menu for less than 60 days per calendar year.'' Accordingly, we decline to shorten the 60-day time period for temporary menu items to 45 days, as suggested by the comment, because doing so would not be consistent with section 403(q)(5)(H)(vii) of the FD&C Act. We did not propose to go beyond the language of section 403(q)(5)(H)(vii) of the FD&C Act by developing a new category of foods called ''seasonal items.'' We disagree that seasonal items should not be exempt if they are routinely offered each year. Whether a ''seasonal item'' would be exempt would be determined by whether the seasonal item satisfied the definition of a ''temporary menu item'' as determined by the total number of consecutive and non-consecutive days per calendar year that the menu item appears on the menu or menu board.

IX. Comments and FDA Response on Proposed § 101.11(b)(1)(i)—Food Subject to the Labeling Requirements

Proposed § 101.11(b) would establish requirements for nutrition labeling of food sold in covered establishments. Proposed § 101.11(b)(1)(i) would provide that the labeling requirement would apply to standard menu items offered for sale in covered establishments. We are finalizing it without change.

Most comments we received about how the nutrition labeling requirements of the rule apply to standard menu items addressed specific labeling requirements (*e.g.,* the provisions of § 101.11(b)(2)(i) for what must be provided on menus and menu boards), and we discuss these comments as they relate to such specific requirements. Immediately following, we discuss one comment more generally directed to the applicability of the labeling requirements of this rule.

(Comment 54) One comment recommended that foods that are preordered and picked up at a later date, such as birthday cakes, boxed lunches, deli trays, and sandwich platters, not be covered by the menu labeling requirements because they are not foods on display, standard menu items, restaurant-type foods, or ordered from a menu or menu board. The comment asserted that restaurant foods are ordered for consumption within a proximate time from when they are ordered, and the person ordering the food intends to eat a portion of the food, whereas catered foods are ordered on behalf of a larger group of people and further ahead of time.

(Response 54) The rule applies to standard menu items offered for sale in covered establishments. The rule defines standard menu item as restaurant-type food that is routinely included on a menu or menu board or routinely offered as a self-service food or food on display (see § 101.11(a)). The definition of ''restaurant-type food'' in § 101.11(a) captures the time when the food will be eaten relative to when it is purchased or picked up (*i.e.,* usually eaten on the premises, while walking away, or soon after arriving at another location) but when the food is ordered in relation to when it is picked up, and how many people will share the food, have no bearing on the applicability of the rule.

X. Comments and FDA Response on Proposed § 101.11(b)(1)(ii)—Food Not Subject to the Labeling Requirements

A. The Proposed Requirements

Proposed § 101.11(b)(1)(ii) would provide that the labeling requirements would not apply to alcohol beverages; items such as condiments that are placed on the table for general use; daily specials; temporary menu items; custom orders; and food that is part of a customary market test. In sections X.B through X.E of this document, we discuss comments on this proposed provision. After considering comments, we are:

- Narrowing the proposed exemption of alcohol beverages from all of the new requirements for nutrition labeling;
- Clarifying that the exemption applies to condiments that are for general use, including those placed on the table or on or behind the counter; and
- Clarifying that the labeling requirements of paragraph (b) do not apply to self-service food and food on display that is offered for sale for less than a total of 60 days per calendar year or fewer than 90 consecutive days in order to test consumer acceptance.

B. Alcohol

1. Alcoholic Beverages

(Comment 55) Some comments agreed with our proposal that alcoholic

beverages should not be covered. Some comments stated that alcoholic beverages should not be considered food within the context of menu labeling. Some comments supporting FDA's proposal to exclude alcoholic beverages referenced Alcohol and Tobacco Tax and Trade Bureau's (TTB's) oversight of alcoholic beverage labels, which includes premarket approval. One comment referred to the district court decision cited in FDA's proposed rule (76 FR 19192 at 19203), *Brown-Forman Distillers Corp.* v. *Mathews,* 435 F. Supp. 5 (W.D.Ky. 1976), as evidence that TTB has jurisdiction over the labeling of alcoholic beverages under the Federal Alcohol Administration Act (FAA Act). Another comment argued that requiring calorie declarations for alcoholic beverages will not affect obesity, because obesity is the result of years of poor diet and lack of exercise. Another comment mentioned a 2011 survey of adult consumers and stated that it showed that most consumers do not want to see calorie counts on drink menus and want to order what they want. The comment did not include or provide a reference for the survey.

In contrast, many comments argued that alcoholic beverages should be covered in the final rule. Some comments asserted that it was not the intent of Congress to exclude alcoholic beverages from the menu labeling requirements. According to these comments, Congress excluded some foods from menu labeling, but did not exclude alcoholic beverages. One comment, referring to a press release of two Senators (Ref. 29), contended that Congress rejected lobbyists who wanted to exclude alcoholic beverages.

Several comments argued that FDA has jurisdiction to require menu labeling for alcoholic beverages and not TTB. According to these comments, Congress directed FDA to require menu labeling for all food, including alcoholic beverages. Some comments maintained that FDA currently has exclusive authority to regulate labeling of certain alcoholic beverages (such as wines containing less than 7 percent alcohol by volume and some beers), and another comment stated that FDA had asserted its authority over alcoholic beverages when FDA and the Federal Trade Commission took action on caffeinated alcohol drinks. One comment maintained that in the absence of a specific prohibition or direct conflict, each Agency can regulate alcoholic beverages in line with its mandate. Another comment stated that the U.S. Supreme Court has noted, ''The courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective,'' citing *Morton* v. *Mancari,* 417 U.S. 535, 551 (1974). Thus, this comment asserted that there is no need to pick and choose between the FAA Act and section 4205 of the ACA because these statutes are capable of coexistence in that they apply to different groups and different practices.

Several comments questioned the applicability of the *Brown-Forman Distillers* v. *Matthews* case to section 4205 of the ACA and contended that Brown-Forman addressed the FAA Act and FDA's authority to impose ingredient labeling on alcoholic beverage labels, not nutrition labeling on menus.

Some comments also argued that FDA's proposed position with regard to alcoholic beverage menu labeling contrasts markedly with its position on meat and poultry menu items, the labels for which are regulated by the USDA. One comment remarked that alcohol used in non-beverage foods, such as bananas foster, would be covered under the proposed rule, so not covering alcohol in foods that are beverages would not be consistent.

Comments supported covering alcoholic beverages on public health grounds. Some comments argued that excluding alcoholic beverages is problematic because it may give the false impression that alcoholic drinks do not contribute to the overall caloric consumption of consumers, working against the underlying goal of section 4205 of the ACA. Other comments remarked that alcoholic beverages contribute a substantial portion of average total calories consumed by Americans, representing the fifth leading source of calories in American adults' diets. One comment stated that alcoholic beverages provide more calories per day on average than many of the food items required to be labeled under this law including pizza, hamburgers, and fried potatoes. Another comment argued that calories in alcoholic beverages count toward overweight and obesity just like calories in foods and other beverages.

According to some comments, if some drinks are labeled and some are not, consumers might be confused, and they would not have the information to compare beverage options and make informed choices. Comments also stated that the calorie content of alcoholic beverages can vary widely and cited studies indicating that consumers are likely to have difficulty identifying lower calorie options. Comments argued that failing to provide consumers with calorie information for alcoholic beverages will make it more difficult for them to follow the 2010 Dietary Guidelines' advice to control total calorie intake to manage body weight.

(Response 55) The final rule does not provide a general exemption for alcoholic beverages. As we stated in the proposed rule, alcoholic beverages are ''food'' under the FD&C Act. Section 201 of the FD&C Act defines ''food'' to include ''articles used for . . . drink for man,'' ''for the purposes of this Act.'' The nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act apply to ''food that is a standard menu item.'' In addition, as some comments indicated, section 403(q)(5)(H)(vii) of the FD&C Act deems the requirements of section 403(q)(5)(H) of the FD&C Act inapplicable to certain foods, and alcoholic beverages are not one of them.

While section 4205 of the ACA amends section 403(q) of the FD&C Act, which generally provides nutrition labeling requirements for certain foods, the nutrition labeling requirements in section 4205 are directed specifically toward standard menu items sold in covered restaurants or similar retail food establishments. Within this context, providing nutrition information for an alcoholic beverage for which other labeling is also regulated by TTB provides the same public health benefit as providing the information for other foods. The provisions of section 4205 of the ACA do not apply to and have no effect on the labels of food products sold in packaged form, including alcoholic beverages regulated by TTB.

Thus, we conclude that the nutrient content disclosure requirements in amended section 403(q)(5) of the FD&C Act for standard menu items offered for sale in covered establishments apply to alcoholic beverages, even though the labeling of alcoholic beverage containers under the FAA Act is regulated by TTB.

FDA's decision to include alcoholic beverages in the menu labeling regulations is not inconsistent with the *Brown-Forman* decision, which addressed the labeling of containers of distilled spirits, wines, and malt beverages subject to the requirements of the FAA Act. This conclusion will not subject the regulated alcohol beverage industry ''to 'duplication and inconsistent standards,' '' a key basis for the *Brown-Forman* decision. (*Brown-Forman* at 14, citing *United States* v. *National Ass'n of Securities Dealers,* 422 U.S. 694, 735 (1975)). The requirements we are finalizing here do not directly conflict with any TTB requirements. As comments pointed out, the nutrition labeling requirements

of section 4205 of the ACA do not apply to and have no effect on the labels of alcoholic beverage containers. In addition, this final rule applies to covered establishments, while the FAA Act's labeling and advertising regulations generally apply to distillers, brewers, rectifiers, blenders, producers, importers, wholesalers, bottlers, and warehousemen of alcoholic beverages (see 27 U.S.C. 205). In short, the two regulatory schemes address different labeling and different actors; they are ''capable of coexistence.'' (See Manconi, cited previously in this document.)

We also recognize that applying this final rule to alcoholic beverages also regulated by TTB is more consistent with the inclusion of meat, poultry, and egg products that are also regulated by USDA.

From a public health perspective, we agree that requiring nutrition labeling of alcoholic beverages that are standard menu items is more likely to enable consumers to compare beverage options and make informed order selections in covered establishments. In addition, while obesity may be related to poor diet generally and a lack of exercise, calories in alcoholic beverages contribute to obesity and overweight just like calories in other foods. Alcoholic beverages contribute a substantial portion of average total calories consumed by American adults (Ref. 3). Table 2–2 in the 2010 Dietary Guidelines for Americans (''2010 Dietary Guidelines''), jointly developed and issued by HHS and the USDA, reports that alcoholic beverages rank sixth in a list of the top 25 food sources of calories among Americans ages 2 years and older, and fifth in a list of the top 25 food sources of calories among adult Americans ages 19 years and older (Ref. 3). The 2010 Dietary Guidelines also discuss alcohol in Chapter Three, entitled ''Foods and Food Components to Reduce'' (Ref. 3).

As to the 2011 survey mentioned in one comment, FDA is unable to draw regulatory conclusions from such a survey without being able to evaluate the survey itself.

(Comment 56) Several comments argued that providing calorie and other nutrition labeling for alcoholic beverages on menus is feasible, and one comment provided an example of a menu which included nutrient content disclosures for alcoholic beverages.

(Response 56) We agree with these comments. We see no basis for why providing calorie and other nutrient content information for alcoholic beverages on menus would be less feasible for covered establishments than providing that same information for most other standard menu items.

(Comment 57) Some comments noted that TTB and FDA currently work together through a Memorandum of Understanding (MOU) and asserted that under this MOU, TTB ensures adequate and non-misleading labeling, and FDA ensures safety. One comment that mentioned this MOU indicated that FDA should not begin to regulate the labeling of alcoholic beverages, while another comment that mentioned the MOU indicated that FDA's coverage of alcoholic beverages would not be inconsistent with the specific language of the MOU.

(Response 57) We agree that FDA's coverage of alcoholic beverages in this context does not affect the delineation of responsibilities between FDA and TTB articulated in the MOU. FDA and TTB continue to work together under the MOU, and FDA has consulted with TTB during this rulemaking.

(Comment 58) A few comments maintained that establishing menu labeling requirements for alcoholic beverages could lead to inconsistencies with TTB requirements. One comment pointed out that TTB has rulemaking underway for ''serving facts'' on alcoholic beverage labels and asserted that, if FDA establishes menu labeling requirements for alcoholic beverages, there could be inconsistencies between nutrition information on labels and menus.

At the time that the proposed rule was issued, alcoholic beverages subject to the labeling regulations under the FAA Act were required to include a statement of average analysis if the label or advertisement made a claim with regard to the calorie or carbohydrate content of the product, and were allowed to include a statement of average analysis for any product. The statement of average analysis listed the number of calories and the number of grams of carbohydrates, fat, and protein per serving (see TTB Ruling 2004–1). In the **Federal Register** of July 31, 2007 (72 FR 41860), TTB published a proposed rule to amend its regulations to require a Serving Facts statement, which would include a statement of calories, carbohydrates, fat, and protein per serving, on alcohol beverage labels. As of December 1, 2014, the TTB proposed rule has not been finalized. On May 28, 2013, TTB issued a ruling (TTB Ruling 2013–2) (Ref. 30) that allows alcohol beverage industry members to provide consumers with nutritional information on alcoholic beverage container labels by using the format of a statement of average analysis or a Serving Facts statement.

The comment stated that TTB's rulemaking should be completed before FDA takes further action or FDA should exclude alcoholic beverages from the menu labeling requirements permanently. According to another comment, the labels currently approved by TTB with a statement of average analysis apply to a small portion of the total volume of beers produced by small brewers. The comment stated that the format is not consistent with FDA's proposed rule, because TTB only requires the disclosure of calories, carbohydrates, protein, and fat, while FDA's proposed rule would require disclosure of additional nutrients. Without agreement on formats, the comment asserted, compliance with FDA proposed menu labeling could contradict TTB guidance. This comment also stated that without a final rule from TTB, beer sold in bottles and cans on display in covered establishments will not be required to bear nutrition information. Comments stated that if FDA decides to cover alcoholic beverages in its menu labeling rule, FDA should coordinate with TTB to ensure consistency.

Some comments that were against including alcoholic beverages maintained that the cost of laboratory analysis for alcoholic beverages, which they assumed would fall on the alcoholic beverage manufacturers, would be significant, especially for alcoholic beverage manufacturers that are small businesses. One comment asserted that the number of brands and styles of beer produced by small brewers varies dramatically in comparison to large brewers, and without in-house laboratories, which the comment believed large breweries would have, covering alcoholic beverages would have a disproportionate effect on small brewers. Several comments argued that sufficiently accurate calorie values for various types of alcohol are readily available from easily accessible databases, such as the USDA's National Nutrient Database for Standard Reference. One comment suggested allowing covered establishments to list estimated or approximate calorie values by category on wine lists rather than by each brand, recognizing that some types of alcoholic beverages, like red or white wines, contain substantially the same calories regardless of variety.

(Response 58) We agree with some comments and disagree with others. As previously mentioned, the nutrition labeling requirements finalized here do not apply to and have no effect on the labels of alcoholic beverage containers. In addition, the new requirements apply

to covered establishments, not to alcoholic beverage manufacturers. In contrast, TTB's ''Serving Facts'' rulemaking would establish new requirements for disclosures on alcoholic beverage labels and would apply to alcoholic beverage bottlers and importers.

Under this final rule, covered establishments have significant flexibility in choosing a reasonable basis for their nutrient content disclosures, which can include a database such as the USDA's National Nutrient Database for Standard Reference (see § 101.11(c) and the discussion in sections XVIII and XIX). The USDA's National Nutrient Database for Standard Reference includes the categories, ''alcoholic beverage, wine, table, red,'' ''alcoholic beverage, wine, table, white,'' among several other general categories for alcoholic beverages. Consistent with our treatment of other standard menu items (see section XVIII of this document), we will allow covered establishments to use these entries as the bases for their nutrient content disclosures for alcoholic beverages that are standard menu items.

In addition, we recognize that statements of average analysis and nutrient content disclosures under current TTB guidance include four nutrients, and our final rule requires that covered establishments make additional nutrient content disclosures for most standard menu items. However, we do not see these differences as conflicts. Nutrient content information on alcoholic beverage labels that is required by or consistent with TTB regulations or guidance could be a reasonable basis for a covered establishment's corresponding nutrient content disclosures. In addition, many alcoholic beverages will be eligible for the simplified format (see discussion re: § 101.11(b)(2)(ii)(B)(*2*)). As provided in § 101.11(c)(1), covered establishments may also choose to use a database such as the USDA National Nutrient Database for Standard Reference as the reasonable basis for making their nutrient content disclosures, including disclosures for nutrients that do not currently appear on alcoholic beverage labels. This should address the comment's concerns about malt beverages or other alcoholic beverages that do not currently include nutrient information. FDA has consulted with TTB on this rulemaking and intends to continue to consult with TTB in the future.

(Comment 59) Some comments recommended that drinks that are ordered by customers at the bar and that are not listed on the menu should be exempt from this rule.

(Response 59) We agree with these comments. The final rule covers alcoholic beverages that are standard menu items that are listed on a menu or menu board. However, we are finalizing the proposed exemption for a subset of alcoholic beverages that are not listed on a menu or menu board. Specifically, § 101.11(b)(1)(ii)(B) of the final rule provides that the labeling requirements of § 101.11(b)(2)(iii) do not apply to those alcoholic beverages that are food on display. Our reasons follow. Because these reasons do not apply equally to alcoholic beverages that are self-service foods, § 101.11(b)(1)(ii)(B) of the final rule clarifies that alcoholic beverages that are self-service foods are covered.

First, it is unclear whether covered establishments could provide nutrient content disclosures for alcoholic beverages on display behind a bar that would assist consumers in making informed and healthful order selections. Covered establishments often serve such beverages in mixed drinks, and the amount of each alcoholic beverage and other mixers they serve to consumers may vary depending on the drink ordered. Section 403(q)(5)(H)(iii) of the FD&C Act requires that calories for self-service food and food on display be declared per serving or per item. Examples of other food on display include: Burrito fillings behind a counter at a burrito restaurant where burritos are made to order and salad ingredients behind a counter at a quick-service salad restaurant where salads are made to order. An employee generally adds a standard serving of each burrito filling or salad ingredient when asked by the customer, *e.g.,* a standard measured weight of meat or a standard spoonful of beans. Nutrient content declarations based on those standardized servings are directly applicable to consumers' order selections.

Even for some foods on display that have servings that vary, *e.g.,* ice cream (where a customer can order one, two, or three scoops) or burrito fillings (where a customer can order extra cheese), the amount the customer receives is generally a simple multiple of a base serving. Ice cream would likely be labeled per scoop and cheese would likely be labeled per standard portion, with extra cheese being double the standard portion.

In contrast, covered establishments with bottles of alcoholic beverages on display behind a bar generally serve varying amounts of alcohol and mixers depending on the establishment's recipes for the various beverages ordered. For example, at a given covered establishment, a martini recipe might have 2 ounces (oz.) of gin and 0.5 oz. vermouth; a cosmopolitan recipe might have 3.5 oz. vodka, a dash of triple sec, a dash of cranberry juice, 1 tsp of sugar, and 1 oz. of lime juice; and a grasshopper recipe might have 1 oz. white crème de cacao, 1 oz. green crème de menthe, and milk or cream to fill the glass (Ref. 31). As a result, the covered establishment does not have a standard serving on which to base a nutrient content declaration for each ingredient that will be directly applicable to all routinely ordered mixed drinks. In addition, recipes for even well-known drinks, like margaritas, may differ from one chain of restaurants to another, and consumers are unlikely to know a particular establishment's recipe while ordering (Ref. 31). It is difficult to see how a consumer would use an establishment's nutrient content disclosure on a bottle of alcohol behind a bar in choosing which mixed drink to order.

Section 403(q)(5)(H)(x)(II)(aa) of the FD&C Act requires FDA to ''consider standardization of recipes and methods of preparation'' and ''variations in ingredients'' in issuing these regulations. Therefore, in finalizing the exemption for alcoholic beverages that do not appear on menus or menu boards, we considered that recipes and methods of preparation for alcoholic mixed drinks are not standardized throughout the industry. In addition, we considered the variations of the amounts of alcoholic beverages and other mixers served in mixed drinks in a given covered establishment.

Alcoholic beverages that are on display differ from other food on display in additional relevant ways. Alcoholic beverages that are on display, particularly bottles of alcohol that are behind a bar, often appear to be on display primarily for decoration or storage, not to aid consumers in selecting among food options. This contrasts with most food that is on display, which is on display in order to aid consumers in selecting among food options (*e.g.,* food choices at a salad bar, cookie varieties at a mall cookie counter). Once covered establishments comply with these new regulations, consumers in covered establishments who look at food on display to decide which displayed food they would like to consume will be able to consider calorie information on signs adjacent to the food and adjust their selection if they choose.

In contrast, bottles of alcoholic beverages often are displayed very close together, layered on top of each other, staged in low lighting or back lighting, or placed very high. In other words,

they are displayed in a manner that does not enable consumers to easily identify the particular alcoholic beverages available to assist them in making their selections. In addition, bartenders often use bottles of alcoholic beverages under the bar—that are not on display—to mix alcoholic drinks. Finally, at many covered establishments that serve alcoholic beverages, mixed drinks and other alcoholic beverages that are not on menus or menu boards are ordered by customers sitting at tables, from which the bar could be completely out of sight.

Based on the above considerations, we are exempting alcoholic beverages that are food on display and are not self-service food. Because these considerations do not apply readily to self-service alcoholic beverages (*e.g.,* bottles of beer in a cooler near the register at a quick service restaurant), self-service alcoholic beverages are covered by the final rule. Therefore, § 101.11(b)(1)(ii)(B) of the final rule provides that the labeling requirements of § 101.11(b)(2)(iii) for standard menu items that are self-service or on display do not apply to alcoholic beverages that are foods on display and are not self-service foods.

C. Condiments

(Comment 60) Several comments recommended that covered establishments provide calorie information for all condiments. Other comments maintained that calorie information should be provided for condiments if they are part of the standard menu item. One comment recommended that the following be added to the provision: ''Condiments and sauces included as an ingredient or standard accompaniment to a menu item must be included in the nutrition information calculated for that item.''

Another comment asked us to clarify that if condiments are provided for optional use, they should not be included in the calorie declaration. As an example, if a container of ketchup is provided on the side with a hamburger and the consumer can decide whether to use it, the container of ketchup should be treated the same as a bottle on the table and be exempted from calorie declaration. Another comment asked that the words ''on the table'' be removed from the provision and that the statute be interpreted to encompass condiments and other items kept behind the counter for general use. This comment explained that its establishment does not typically have tables as most of the business is take-out, and the condiments are kept behind the counter and available to the consumer upon request.

One comment suggested that the exemption for condiments include only those self-serve items that are calorie free or that have a Nutrition Facts label. Another comment recommended that self-serve restaurants have the flexibility to determine which items can reasonably be considered condiments for general use, noting that many of its restaurants have an extensive ''spice bar'' that contains dozens of different spices, seasonings, and other condiments that any customer can use, regardless of that customer's order or food selections. The comment maintained that the regulation should be clear that all spices and seasonings fall in this exempt category.

(Response 60) We are clarifying the exemption for condiments. Section 403(q)(5)(H)(vii)(I)(aa) of the FD&C Act provides that the requirements of section 403(q)(5)(H) of the FD&C Act do not apply to ''items that are not listed on a menu or menu board (such as condiments and other items placed on the table or counter for general use).'' We affirm our tentative conclusion in the proposed rule that, given the phrase ''for general use,'' it is reasonable to interpret section 403(q)(5)(H)(vii)(I)(aa) of the FD&C Act to apply to foods, such as many condiments, that are available for use by any customer in the covered establishment, regardless of the customer's particular order or food selection (76 FR 19192 at 19205). For example, it is reasonable to apply section 403(q)(5)(H)(vii)(I)(aa) of the FD&C Act to maple syrup that is provided in a bulk container or bottles of ketchup that are available for any customer to add to his or her food.

However, we agree that the calorie declaration for a standard menu item must include the number of calories in the condiment if the condiment is used as a component in the standard menu item, as usually prepared and offered for sale. In such situation, the nutrient declarations for the standard menu item in the written nutrition information required by section 403(q)(5)(H)(ii)(III) of the FD&C Act and § 101.11(b)(2)(ii) must also include the nutrient amounts from the condiment because the condiment is used as a component in the standard menu item. The exemption in section 403(q)(5)(H)(vii)(I)(aa) of the FD&C Act does not apply to condiments that are part of a standard menu item, as the standard menu item is usually prepared and offered for sale. For example, if a covered establishment ordinarily offers for sale burgers containing ketchup and mayonnaise added by the establishment, the ketchup and mayonnaise would be part of the standard menu item as usually prepared and offered for sale, and the calorie declaration for the standard menu item would include the calories in the ketchup and mayonnaise. Likewise, if a covered establishment ordinarily provides each customer who orders pancakes with a single serving container of maple syrup, the maple syrup would be part of the standard menu item as usually prepared and offered for sale, and the calorie declaration for the standard menu item would include the calories in the single serving container of maple syrup. Similarly, as noted previously in this document, in these situations, the nutrient declarations for the standard menu item in the written nutrition information required by section 403(q)(5)(H)(ii)(III) of the FD&C Act and § 101.11(b)(2)(ii) must also include the nutrient amounts from the condiment because the condiment is used as a component in the standard menu item.

We see no difference between a condiment brought to the table for general use and a condiment kept behind the counter for general use (and then provided to a customer who requests it), provided that such condiments are not listed on the menu or menu board separately or as part of a standard menu item. Therefore, we agree that condiments that are behind the counter for general use are exempt from the nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act under section 403(q)(5)(H)(vii)(I)(aa) of the FD&C Act. For clarity, we have revised § 101.11(b)(1)(ii) to explicitly provide that the labeling requirements in paragraph (b) do not apply to items such as condiments that are for general use, including those placed on the table *or on or behind the counter.* (Emphasis added.) As revised, § 101.11(b)(1)(ii) includes condiments placed ''on'' the counter in accordance with section 403(q)(5)(H)(vii)(I)(aa) of the FD&C Act and in order to take into account varying business practices.

We disagree that the exemption for condiments should include only those self-serve items that are calorie free or that have a Nutrition Facts label. The exemptions under § 101.11(b)(1)(ii) are based on the language of section 403(q)(5)(H)(vii) of the FD&C Act. Section 403(q)(5)(H)(vii) of the FD&C Act generally provides that the nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act do not apply to certain foods, including certain condiments. Section 403(q)(5)(H)(vii) of the FD&C Act does not qualify such exemptions based on the caloric content of the food or the fact that some food would be available in packaged form that provides a Nutrition Facts label.

However, we note that under § 101.11(b)(2)(iii)(C), a covered establishment would not be required to provide the written nutrition information required by section 403(q)(5)(H)(ii)(III) of the FD&C Act and § 101.11(b)(2)(ii) for a self-service food or food on display that is a packaged food insofar as it bears nutrition labeling information required by and in accordance with § 101.11(b)(2)(ii) and the packaged food, including its label, can be examined by a consumer before purchasing the food.

We also note that spices and seasonings (such as crushed dried peppers) are considered condiments that are exempt from the requirements of section 403(q)(5)(H) of the FD&C Act under section 403(q)(5)(H)(vii)(I)(aa) of the FD&C Act, provided that they are for general use by customers regardless of their particular order selection.

D. Daily Specials, Temporary Menu Items, Custom Orders, and Food That Is Part of a Customary Market Test

(Comment 61) Several comments agreed with the proposed exemption for daily specials. One comment disagreed with the proposed exemption because the burden to calculate the calories and other nutrition information is not so great for daily specials to justify this exemption. The comment maintained that consumers often buy what is on sale and that excluding daily specials from the requirements of section 403(q)(5)(H) of the FD&C Act would undermine the purpose of the statute.

One comment opposed the proposed exemption for temporary menu items because temporary menu items represent a large portion of what is ordered on a single day at some establishments.

Several comments agreed with the proposed exemption for food that is part of a customary market test. One comment opposed the proposed exemption because chain restaurants test market their menu items carefully before they mass market menu items and the determination of the nutrient content should be part of that process. The comment asserted that disclosing the calorie content of the food may impact the consumer's decision to purchase the food and may impact the establishment's decision whether to include that food on the regular menu.

(Response 61) We are retaining in § 101.11(b)(1)(ii) the exemptions for daily specials, temporary menu items, custom orders, and food that is part of a customary market test. Section 403(q)(5)(H)(vii) of the FD&C Act specifically exempts such items from the requirements of section 403(q)(5)(H) of the FD&C Act regardless of the factors identified by the comments, such as how the burden to calculate calories for these items compares to the burden to calculate calories for standard menu items; the tendency of consumers to buy what is on sale; and whether a chain restaurant could determine nutrition information.

Section 403(q)(5)(H)(vii) of the FD&C Act generally provides that the nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act do not apply to certain foods, including daily specials, temporary menu items appearing on the menu for less than 60 days per calendar year, custom orders, and food that is part of a customary market test appearing on the menu for less than 90 days under terms and conditions established by FDA. Accordingly, § 101.11(b)(1)(ii) provides that the labeling requirements of § 101.11(b) do not apply to such foods and § 101.11(a) defines the terms for such foods. We note that, as discussed in Response 62, self-service food and food on display that are temporary menu items or part of a customary market test, but do not appear on a menu, are also exempt from the requirements of section 403(q)(5)(H) of the FD&C Act because these foods are not standard menu items.

However, neither section 403(q)(5)(H) of the FD&C Act nor this rule would prevent a covered establishment from voluntarily declaring calories or providing written nutrition information for condiments, daily specials, temporary menu items, or food that is part of a customary market test.

Regarding daily specials, we note that we would not consider an item that is offered every week on a particular day (*e.g.,* the Monday special) to be a ''daily special'' because it is being routinely offered for sale (*i.e.,* every Monday). In addition, we would not consider a standard menu item, as defined in this rule, to be a ''daily special'' if it is offered at a discounted price on a particular day (*e.g.,* a turkey club sandwich that is a standard menu item and normally costs 5 dollars, but is specially advertised as costing only 4 dollars on Fridays).

(Comment 62) In the proposed rule (76 FR 19192 at 19205), we noted that self-service food and food on display that do not appear on menus or menu boards would not be considered temporary menu items or food that is part of a customary market test. Therefore, even if a self-service food or food on display that does not appear on a menu or menu board is only offered by a covered establishment for a limited time, such as a pumpkin spice muffin available only in November, we tentatively concluded that the nutrition information declaration requirements in section 403(q)(5)(H) of the FD&C Act would still apply.

Several comments that addressed the exemption in proposed § 101.11(b)(1)(ii) for temporary menu items and food that is part of a customary market test considered that this exemption should apply to self-service food and food on display even though such foods may not ''appear[ ] on a menu'' as described in section 403(q)(5)(H)(vii) of the FD&C Act. These comments said that Congress excluded temporary menu items and customary market test items from the nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act because it recognized that restaurants should be able to test products (many of which fail and are discontinued quickly) without incurring the significant costs associated with changing their menu and compiling nutritional information. The comments considered that this same reasoning applies to temporary menu items and customary market test items offered in self-service restaurants (whether the restaurant displays items on a menu, menu board, or individual signs). The comments asserted that for buffet-type restaurants, there would be significant costs in attempting to improve and change their menus for temporary menu items and food that is being market tested and that these costs would not be incurred by other kinds of non-buffet-type restaurants.

(Response 62) We agree with these comments that the statutory exemptions for temporary menu items appearing on the menu for less than 60 days per calendar year and customary market test items appearing on the menu for less than 90 days apply to self-service foods and foods on display that fall into those categories, as defined in § 101.11(a). We also agree that a self-service food and food on display that does not appear on a menu or menu board but otherwise meets the definition for temporary menu items or food that is part of a customary market, in that the food is offered for sale in a covered establishment for less than a total of 60 days per calendar year or fewer than 90 consecutive days in order to test consumer acceptance, should not be required to comply with the requirements of section 403(q)(5)(H) of the FD&C Act and § 101.11. The requirements of section 403(q)(5)(H) of the FD&C Act and § 101.11 apply to foods that are standard menu items. However, self-service foods and foods on display that do not appear on a menu or menu board, but otherwise meet the definitions for temporary menu items or

food that is part of customary market test, along with the foods described in section 403(q)(5)(H)(vii) of the FD&C Act, do not meet the definition for a standard menu item in § 101.11(a) because such self-service foods and foods on display are neither ''routinely included on a menu or menu board'' nor ''routinely offered as a self-service food or food on display.'' Like temporary menu items or food that is part of a customary market test appearing on a menu or menu board, as described in section 403(q)(5)(H)(vii) of the FD&C Act, self-service foods and foods on display that do not appear on a menu or menu board but otherwise meet the definitions for temporary menu items or food that is part of a customary market are offered for a limited time and are subject to variation and discontinuation depending on the seasonality and consumer response. Thus, these foods, like the foods described in section 403(q)(5)(H)(vii) of the FD&C Act, are not standard menu items and the requirements of this rule do not apply to such foods.

For these reasons, we are modifying § 101.11(b)(1)(ii)(A). First, we are specifying in § 101.11(b)(1)(ii)(A) that the labeling requirements in paragraph (b) do not apply to foods that are not standard menu items. Second, we are specifying in § 101.11(b)(1)(ii)(A)(*1*) that such foods that are not standard menu items include items such as condiments that are for general use, including those placed on the table or on or behind the counter; daily specials; temporary menu items; custom orders; and food that is part of a customary market test. Third, we are specifying in § 101.11(b)(1)(ii)(A)(*2*) that such foods that are not standard menu items also include self-service food and food on display that is offered for sale for less than a total of 60 days per calendar year or fewer than 90 consecutive days in order to test consumer acceptance.

E. Additional Comments on Food That Is Part of a Customary Market Test

(Comment 63) Some comments asked us to clarify that if a food is tested in more than one location, the 90-day period is applied to each location. These comments maintained that it is common for restaurants and similar retail food establishments to conduct iterative tests to evaluate the performance of a menu item and change the menu in light of test results. For example, the results of iterative tests may lead to ''changes in product makeup, including size, shape, taste profile, and preparation,'' with accompanying changes to the underlying nutrient content. The comment asked us to clarify that a food that changes in such a manner during a market test is a new food, and the 90-day period would begin again. One comment asked us to confirm that a market test may be conducted in multiple locations and that the 90-day period starts when the testing begins in a particular location.

(Response 63) As we discussed in the proposed rule (76 FR 19192 at 19205) and as suggested by the comments, in some cases, a chain of restaurants and similar retail food establishments may test a new product in different locations within the chain and in more than one region of the country at different times. We conclude that a ''customary market test,'' for the purposes of § 101.11, refers to a test in a single covered establishment. Therefore, we agree with the comments that the 90-day period for the food that is part of a customary market test applies to each covered establishment that offers for sale food that is part of a customary market test.

Further, we recognize that restaurants and similar retail food establishments may change the foods that they are market testing in an iterative process. Therefore, we agree that if a food changes in ways such as those noted in the comments (*e.g.,* changes in product makeup, including size, shape, taste profile, and preparation), it would be a new food and the 90-day period would begin again. We would consider the food to be a new food if it is not made with the same general recipe or same ingredients or otherwise has a significant change in the nutrient profile during the market test. For example, we would consider a soup prepared without meat, and a soup prepared with added sausage, to be different foods and would expect differences between the nutrient profiles of these different foods.

XI. Comments and FDA Response on Proposed § 101.11(b)(2)(i)(A)(*1*) to (b)(2)(i)(A)(*3*)—General Requirements for Calorie Declaration on Menus and Menu Boards

Proposed § 101.11(b)(2)(i)(A)(*1*) to (b)(2)(i)(A)(*3*) would require that covered establishments declare the number of calories contained in each standard menu item listed on the menu or menu board, as usually prepared and offered for sale in the following manner:

- The number of calories must be listed adjacent to the name or the price of the associated standard menu item, in a type size no smaller than the name or the price of the associated standard menu item, whichever is smaller, in the same color, or a color at least as conspicuous as the name of the associated standard menu item, and with the same contrasting background as the name of the associated standard menu item (proposed § 101.11(b)(2)(i)(A)(*1*)).
- The calories must be declared to the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero (proposed § 101.11(b)(2)(i)(A)(*2*)).
- The term ''Calories'' or ''Cal'' must appear as a heading above a column listing the number of calories for each standard menu item or adjacent to the number of calories for each standard menu item. If the term ''Calories'' or ''Cal'' appears as a heading above a column of calorie declarations, the term must be in a type size no smaller than the smallest type size of the name or price of any menu item on that menu or menu board in the same color or a color at least as conspicuous as that name or price and in the same contrasting background as that name or price. If the term ''Calories'' or ''Cal'' appears adjacent to the number of calories for the standard menu item, the term ''Calories'' or ''Cal'' must appear in the same type size and in the same color and contrasting background as the number of calories (proposed § 101.11(b)(2)(i)(A)(*3*)).

In the following paragraphs, we discuss comments on these proposed provisions. After considering the comments, we are:

- Revising § 101.11(b)(2)(i)(A) to specify that in the case of multiple-serving standard menu items, the calorie declaration must be for the whole menu item as listed on the menu or menu board, as usually prepared and offered for sale (*e.g.,* ''pizza pie: 1600 calories''), or per discrete serving unit as long as the discrete serving unit (*e.g.,* pizza slice) and total number of discrete serving units are declared on the menu or menu board, and the menu item is usually prepared and offered for sale divided in discrete serving units (*e.g.,* ''pizza pie: 200 cal/slice, 8 slices'').
- Revising § 101.11(b)(2)(i)(A)(*1*) to provide additional flexibility for the contrasting background used for the calorie declaration;
- Making a conforming editorial change to the requirement for the color used for the calorie declaration for grammatical consistency; and
- Making an editorial correction for clarity to insert ''the type size of'' between ''no smaller than'' and ''the name or the price'' in § 101.11(b)(2)(i)(A)(*1*).

(Comment 64) Many comments regarding the proposed requirement that the number of calories contained in each standard menu item listed on the

menu or menu board be declared as usually prepared and offered for sale addressed the discussion in the proposed rule regarding how the calorie labeling requirements on menus and menu boards would apply to multiple-serving foods that are standard menu items (76 FR 19192 at 19203–19204). Many comments agreed with the view we expressed in the proposed rule that section 403(q)(5)(H) of the FD&C Act requires that calories be declared for standard menu items regardless of how many servings are included in the item (76 FR 19192 at 19203). The comments asserted that servings vary by product and by portions taken by consumers. One comment considered that if a menu item is to be shared, it would be easier for consumers to determine how many people will share the item and divide the calories accordingly than for the restaurant to choose how many servings are in a menu item. The comment said that we should not allow restaurants to choose how many servings are in a menu item.

Many other comments opposed listing the calories for the entire standard menu item and instead supported the listing of calories per serving. Some comments asserted that listing calories per serving would be less confusing, would be consistent with calorie declarations on packaged food, and would not require consumers to do a calculation. One comment agreed with our determination that a multiple-serving food is a standard menu item but disagreed with our tentative conclusion that the calorie declaration should be for the entire multiple-serving food because providing calories for the entire multiple-serving food would not be helpful and would be detrimental for those who need the information per serving (*e.g.,* diabetics). A few comments asked us to provide an option to permit either the declaration of calories for the entire multiple-serving menu item, or the declaration of the number of servings and the calories per serving. As an example, one comment suggested that a restaurant selling a four-serving family-style platter of pasta could comply either by disclosing that the whole menu item contains 2,000 calories, or by disclosing that the menu item consists of 4 servings, 500 calories per serving.

One comment pointed out that if we required calorie declaration for an entire multiple-serving food, nutrition information would be inconsistent in some instances. For example, a cheesecake from a display case would have different nutrition information than the same cheesecake in prepackaged form, because the first would list calories for the entire item whereas the second would list calories per serving. One comment suggested that, for foods that are not appetizers or desserts that are intended to serve more than one person, calorie disclosure should include the number of persons intended to be served and the calorie content per serving.

A few comments recommended that calories for pizza be listed per slice. One comment reported that it received complaints when it provided calorie information for the entire listed pizza. The comment provided a report of consumer research showing that 60 percent of consumers preferred calorie information per slice. The report of this survey was submitted with the comment (Ref. 32). Some comments referred to our previous statements that nutrition information should be declared per serving. For example, in our proposed rule on ''Food Labeling: Serving Sizes,'' we stated that for ''[f]oods in large discrete units,'' ''the household measure most meaningful for these products is a fraction of the whole unit.'' (56 FR 60394 at 60410, November 27, 1991). Another comment referred to statements in our 2008 ''Guidance for Industry: A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods (the 2008 restaurant labeling guide) (Ref. 10) that generally the nutrition information should be presented on a per serving basis. For example, the 2008 restaurant labeling guide states that ''[i]t is especially important that the basis be declared when a food is available in more than one size serving (*e.g.,* pizza that is available whole and by slice). . . . The restaurant may provide additional information, such as '8 slices per medium 16-inch pizza, 1 slice contains . . .' to help consumers put nutrition information in context.''

Other comments urged us to clarify that a covered establishment can voluntarily provide nutrition information per serving. These comments suggested that we revise the rule to indicate that fact. These comments suggested adding the following to § 101.11(b)(2)(i)(A): ''(5) For items that could serve more than one person, such as a large pizza or a bucket of chicken, calories must be listed per standard menu item as offered for sale and listed on the menu or menu board or as placed on display. In addition, restaurants and similar retail food establishments may also voluntarily provide nutrition information per serving.''

(Response 64) Listing calories for multiple-serving standard menu items as usually prepared and offered for sale by a covered establishment is consistent with section 403(q)(5)(H) of the FD&C Act. As discussed in the proposed rule, section 403(q)(5)(H) of the FD&C Act requires covered establishments to disclose calorie information for standard menu items as usually prepared and offered for sale, regardless of how many servings are included in the menu item (76 FR 19192 at 19203).

Based on the comments that supported calorie declarations for multiple-serving standard menu items ''per serving,'' the complexity of consumer eating habits and preferences described by the comments, and the variety of ways that covered establishments may choose to usually prepare and offer their foods for sale, we have revised the rule's calorie declaration requirements for multiple-serving standard menu items on menus and menu boards.

Where a multiple-serving standard menu item is usually prepared and offered for sale divided in discrete serving units (*e.g.,* slices of pizza), we are allowing covered establishments to provide the calorie declaration per discrete serving unit, subject to some additional requirements. If a covered establishment declares calories for a multiple-serving standard menu item per discrete serving unit, the establishment must also declare the discrete serving unit and the total number of discrete serving units in the menu item on the menu or menu board so that the consumer can make a fully-informed decision before selecting the item.

We are allowing calorie declarations per discrete serving unit for multiple-serving standard menu items that are usually prepared and offered for sale divided in discrete serving units because such division will likely enable consumers to easily identify the discrete serving unit (*e.g.,* pizza slice) and therefore keep track of the number of serving units consumed. Pizza slices that come in a pie, or breadsticks that come in a bunch (*e.g.,* ''pizza pie: 200 cal/slice, 8 slices;'' ''breadsticks: 150 cal/stick, 5 sticks'') are examples of multiple-serving standard menu items that are usually prepared and offered for sale divided in discrete serving units. If consumers share such a menu item, the discrete serving units provide a distinct division along which portions can be divided, thereby allowing consumers to keep track of calories consumed by either adding or multiplying the per discrete serving unit calorie declaration based on the number of serving units consumed. Providing the number of calories per discrete serving unit and the total number of discrete serving unit contained in the menu item for

multiple-serving standard menu items that are usually prepared and offered for sale divided in discrete units enables consumers to determine the number of calories they may actually consume and therefore enables consumer to make informed dietary choices.

However, where a multiple-serving standard menu item is not usually prepared and offered for sale divided in discrete serving units, covered establishments must declare calories for the entire menu item listed on the menu or menu board, as usually prepared and offered for sale. We disagree with the comment that said a calorie declaration for a whole multiple-serving standard menu item would be unhelpful or detrimental. If consumers decide to share a multiple-serving standard menu item, they can divide the total number of calories by the number of individuals sharing it. We clarify—as one comment suggested—that for multiple-serving standard menu items that are not usually prepared and offered for sale divided in discrete serving units, we would not object if a covered establishment decided to voluntarily declare calories per serving, in addition to the calories for the entire standard menu item.

(Comment 65) A few comments recommended that calories be declared per reference amount customarily consumed (RACC) or by household measure. A RACC represents the amount of food customarily consumed at one eating occasion (§ 101.12 (21 CFR 101.12)). A few comments considered that listing calories per serving based on the RACC would be consistent with the labeling of packaged food. One comment noted that customers are used to seeing information per serving even though actual consumption may not be aligned with the RACC.

(Response 65) We assume that ''household measure'' refers to measures such as ''cups'' or ''tablespoons.'' RACCs represent the amount of food customarily consumed at one eating occasion and are calculated for a variety of foods purchased by consumers in establishments such as grocery stores (see § 101.12). RACCs are based on data set forth in national food consumption surveys and other sources of information on serving sizes of food, including serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations, serving sizes used by manufacturers and grocers, and serving sizes used by other countries (§ 101.12(a)). We developed RACCs as the basis for determining serving sizes for specific products for the purpose of declaration of nutrition information on product labels.

We disagree that calories for standard menu items should be declared per RACC or by household measure. Section 403(q)(5)(H) of the FD&C Act requires covered establishments to disclose the number of calories contained in a standard menu item ''as usually prepared and offered for sale.'' Although many standard menu items may have an associated RACC, others may not. Even if some standard menu items have an associated RACC, each covered establishment is free to choose the amount of food offered for sale in its standard menu items, and section 403(q)(5)(H) of the FD&C Act does not require covered establishments to prepare and offer standard menu items in particular amounts, such as RACCs.

(Comment 66) Some comments considered that calories should be declared for each size of a menu item (such as ''upgrades'' or ''upsized options'' and ''downsized options'') offered on menus and menu boards. Some comments linked the requirement to declare calories for different sizes to different prices—*e.g.,* by considering that calories must be declared for any size option that has a distinct price on the menu or menu board. Some comments specifically addressed fixed combination meals and considered that calories should be declared for fixed combination meals available in multiple sizes.

One comment asked us to allow the restaurant to list calories for a 6-inch version of a sandwich and provide a statement on the menus and menu boards that the 12-inch sandwich is double that amount.

(Response 66) The calorie labeling requirements of § 101.11(b)(2)(i)(A) apply to each standard menu item listed on the menu or menu board, as usually prepared and offered for sale. Thus, if a standard menu item (such as fries or onion rings) is listed on the menu or menu board in more than one size (such as ''small'' and ''large''), the menu or menu board must provide calories for each size, following the format requirements of § 101.11(b)(2)(i)(A)(*1*), (b)(2)(i)(A)(*2*), and (b)(2)(i)(A)(*3*). Likewise, if a fixed combination meal (*i.e.,* a meal consisting of components that are not subject to a consumer's selection, such as a burger and fries) is listed on the menu or menu board in more than one size (*e.g.,* a hamburger with small fries or large fries), the menu or menu board must provide calories for each size of the fixed combination meal, also following the format requirements of § 101.11(b)(2)(i)(A)(*1*), (b)(2)(i)(*A*)(*2*), and (b)(2)(i)(*A*)(*3*).

If a 6-inch sandwich and a 12-inch sandwich are both standard menu items listed on a menu or menu board, or are on display in a covered establishment, the establishment must disclose the number of calories for each sandwich size, following the format requirements of § 101.11(b)(2)(i)(A)(*1*), (b)(2)(i)(A)(*2*), and (b)(2)(i)(A)(*3*) or § 101.11(b)(2)(iii) as applicable, unless the sandwich is exempt from the nutrition labeling requirements under section 403(q)(5)(H)(vii) of the FD&C Act.

(Comment 67) One comment interpreted the phrase ''as usually prepared'' within ''as usually prepared and offered for sale'' in proposed § 101.11(b)(2)(i)(A) to be a ''standard formula,'' ''recommended formula,'' ''standard build,'' or any other term that means a predetermined method of preparation designed to ensure that all menu offerings are nutritionally consistent and uniform throughout all covered establishments in a chain.

One comment agreed that the number of calories for a standard menu item should be measured based on how the standard menu item is usually prepared and offered for sale, but expressed concern about build-as-you-go menu items. The comment explained that, a covered establishment might post the number of calories for a build-as-you-go menu item as an ''undressed'' sandwich (the comment did not define this term), giving the false impression that the sandwich has fewer calories than it may actually contain as prepared by the covered restaurant and then consumed by a customer. This comment contended that this type of sandwich should be considered a variable menu item with calories posted as a range (*i.e.,* in accordance with proposed § 101.11(b)(2)(i)(A)(*4*)) that includes the undressed sandwich and the fully built one, because there is standardization with respect to the specific amount of each particular food item or condiment that consumers can add to the build-as-you-go menu item. As evidence for this view, the comment referred to the standard extra charge for items such as an extra scoop of guacamole.

(Response 67) We agree that ''standard build'' or ''recommended formula'' is consistent with the term ''as usually prepared and offered for sale.'' However, it is the build that is standard to any given covered establishment, rather than recommendations or standards by or from the chain as a whole, that dictates the nutrition information that would be required to be declared for standard menu items in a particular covered establishment.

Regarding the comment expressing concern about build-as-you-go menu

items, we first note that a build-as-you-go menu item, such as a sandwich with the option of adding different fixings, that is a standard menu item, likely would be considered a variable menu item. As discussed previously in this document (see sections VIII.B and VIII.D), § 101.11(a) defines the terms, ''standard menu item'' and ''variable menu item.'' A variable menu item is defined in § 101.11(a) as a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item. A variable menu item is one type of standard menu item. In the proposed rule, we provided examples of ''standard menu items''—*e.g.,* a hamburger, a combination meal, a specific type of pizza (*e.g.,* deluxe pizza), potato salad that is routinely offered at a salad bar, pancakes that are routinely offered at a buffet, and pudding that is routinely offered at a cafeteria line (76 FR 19192 at 19203). We also provided examples of variable menu items—*i.e.,* foods that may have flavoring options (*e.g.,* a milkshake that is available in vanilla, chocolate, or strawberry flavors) or topping options (*e.g.,* pizza prepared with a selection of toppings) (76 FR 19192 at 19204). In the following paragraphs, we provide additional examples relevant to build-as-you-go menu items and explain how the calorie labeling requirements of § 101.11(b)(2)(i)(A) would apply.

A standard menu item that is listed on a menu or menu board that is not a variable menu item, in that it does not come in different flavors, varieties, or combinations that are listed as a single menu item, (*e.g.,* a turkey and Swiss cheese sandwich on whole wheat bread with mustard), would be subject to the calorie declaration format requirements of § 101.11(b)(2)(i)(A)(*1*) to (b)(2)(i)(A)(*3*), but would not be subject to the additional format requirements for variable menu items (proposed § 101.11(b)(2)(i)(A)(*4*)), established in this rule as § 101.11(b)(2)(i)(A)(*4*) through (b)(2)(i)(A)(*8*); see the discussion of the additional format requirements for variable menu items in section XII). However, a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item on a menu or menu board (*e.g.,* a ''turkey and cheese sandwich,'' with different options for the type of bread (*e.g.,* whole wheat or white), cheese (*e.g.,* Swiss, provolone, cheddar), fixings (*e.g.,* onions, lettuce, tomato), and condiments (mustard, ketchup, mayonnaise)) would be a variable menu item subject to both the general calorie declaration format requirements of § 101.11(b)(2)(i)(A)(*1*) to (b)(2)(i)(A)(*3*) for all standard menu items and the additional format requirements for variable menu items as applicable in § 101.11(b)(2)(i)(A)(*4*) through (b)(2)(i)(A)(*8*).

(Comment 68) Several comments agreed with proposed § 101.11(b)(2)(i)(A)(*2*) and the flexibility in proposed § 101.11(b)(2)(i)(A)(*3*) to permit the abbreviation ''Cal'' for calories.

Several comments addressed the placement provisions for the calorie declarations in proposed § 101.11(b)(2)(i)(A)(*1*) and (b)(2)(i)(A)(*3*). A few comments agreed that the number of calories be posted next to the name or price of the menu item (proposed § 101.11(b)(2)(i)(A)(*1*)) and that the term ''Calories'' or ''Cal'' be next to the number of calories (proposed § 101.11(b)(2)(i)(A)(*3*)). One comment found that customers in its restaurants confused calorie declarations with price declarations and noted that declaring calories in the same font, size, and contrast as the price would create confusion, even if the color is different.

Another comment from a chain restaurant found that consumers in its restaurants were confused when calories were posted next to the name of the menu item and thought the number of calories was the order number; to address this confusion, the restaurant put the number of calories after the price and in a different color, font, and size. This comment emphasized its 3 years of experience with posting calorie declarations and provided examples of its menu boards to demonstrate how it communicates calorie information about its menu offerings. This comment agreed that calorie information should be listed in a manner that allows the customer to easily identify the calories associated with a particular menu item, but disagreed that listing calories adjacent to a menu item is the only way (or even the best way) for customers to understand the information associated with their menu choice. This comment asserted that it had specifically learned from practical application and guest feedback that this generally is not the most useful method of providing caloric information. This comment suggested that the rule require a logical and clear association between the menu item and calorie declaration, but provide flexibility for how that logical and clear association occurs.

(Response 68) We appreciate receiving the sample menu boards from the comment as a means of sharing experience with us. However, we are retaining in § 101.11(b)(2)(i)(A)(*1*) the requirement that the number of calories be listed adjacent to the name or the price of the associated standard menu item. This requirement is consistent with section 403(q)(5)(H)(ii)(I)(aa) of the FD&C Act, which requires that the calorie declaration be ''adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item.'' Placing calorie declarations adjacent to the names of standard menu items provides a clear and logical association between the standard menu item and the calorie declaration and helps to ensure that consumers are able to see the declarations. In addition, § 101.11(b)(2)(i)(A)(*3*) provides that the term ''Calories'' or ''Cal'' must appear as a heading above a column listing the number of calories for each standard menu item or adjacent to the number of calories for each standard menu item. As such, § 101.11(b)(2)(i)(A)(*3*) helps to further ensure that the calorie declaration is clearly associated with a particular standard menu item, and the required use of the term ''Calories'' or ''Cal'' will help inform consumers that the number listed refers to calories. Section 101.11(b)(2)(i)(A)(*1*) also provides flexibility by requiring a covered establishment to declare calories adjacent to either the name or the price of the standard menu item. This flexibility is consistent with what one comment described doing in a restaurant. As finalized, § 101.11(b)(2)(i)(A)(*1*) also provides sufficient flexibility to accommodate different types of menus and menu boards and the various ways that standard menu items may be listed on menus and menu boards. Specifically, in this rule § 101.11(b)(2)(i)(A)(*1*):

- Provides flexibility to use a color ''at least as conspicuous'' as that of the name of the associated standard menu item and, thus, allows for the use of a different color;
- Provides flexibility to use a contrasting background ''at least as conspicuous'' as that used for the name of the associated standard menu item and, thus, allows for the use of a different contrasting background (see Response 73);
- Provides flexibility to use a type size ''no smaller than the type size of the name or price'' of the associated standard menu item and, thus, allows for the use of a different type size; and
- Does not restrict the font style.

We also note that the sample menu boards of the chain restaurant provided in the comment generally followed the provisions of the proposed rule in terms of type size and placement of calorie declarations. For example, the menu boards listed calorie declarations

adjacent to the names of standard menu items in a type size no smaller than the name or the price of the associated standard menu item, whichever is smaller, in a column with a heading ''Calories.'' Therefore, while the comment opposed the requirement that calorie declarations be placed adjacent to the names of standard menu items on menus and menu boards, the menu boards of the chain restaurant, nevertheless, generally used the same method of calorie declaration on menus and menu boards as required by this rule.

(Comment 69) In the proposed rule, we tentatively concluded that some packaged foods offered for sale in covered establishments are covered by the menu labeling requirements (see 76 FR 19192 at 19217, proposed § 101.11(b)(2)(iii)(C)). For example, a covered establishment may list ''chips'' on its menu board, referring to packaged bags of chips that are available as self-service foods or foods on display within the establishment. In this situation, the establishment would be required to disclose on the menu board calorie information for the packaged chips. In addition, if a covered establishment lists on its menu or menu board a combination meal that includes a packaged food, the establishment would be required to disclose the total calorie information for the combination meal, including the packaged food.

One comment agreed with requiring the total calorie information of a combination meal that includes a packaged food to include the calories for the packaged food. Another comment disagreed that calories should be declared on a menu or menu board for packaged foods, particularly packaged soft drinks.

(Response 69) As required by section 403(q)(5)(H) of the FD&C Act, covered establishments must provide calorie information for all standard menu items, including foods that are packaged. In addition, sections 403(q)(5)(H)(ii)(I)(aa) and (II)(aa) of the FD&C Act requires that covered establishments disclose the number of calories contained in a standard menu item, ''as usually prepared and offered for sale.'' As such, we agree that a covered establishment that lists on its menu or menu board a combination meal that includes a packaged food must disclose the total number of calories in the combination meal, including the calories for the packaged food.

(Comment 70) One comment stated that the total calorie declaration for a standard menu item must include all ingredients of a standard menu item, as it is usually prepared and offered for sale, *e.g.,* for a teaspoon of sugar added to oatmeal and salad dressings served on or with salad.

(Response 70) We agree that the total calorie declaration for a standard menu item must include all ingredients of the standard menu item, as it is usually prepared and offered for sale, *e.g.,* for a teaspoon of sugar added to oatmeal and salad dressings served on or with salad. As with the scenario discussed in Response 69 for a combination meal that includes a packaged food, doing so is required by section 403(q)(5)(H) of the FD&C Act and by sections 403(q)(5)(H)(ii)(I)(aa) and (II)(aa) of the FD&C Act.

(Comment 71) One comment suggested that we require that covered establishments provide the Reference Daily Intakes (RDIs) of calories, fat, cholesterol, and ''salt'' on menus and menu boards. The comment acknowledged that there is no RDI for sugar, but requested that it nonetheless be included on menus and menu boards. The comment also recommended that menus and menu boards only list percent Daily Value (DV) of calories, fat, cholesterol, sugar, and ''salt'' and not list vitamins and minerals because ''too many details may lead to information overload and defeat the purpose.''

(Response 71) We disagree with the comment's suggestions, and we are not requiring covered establishments to include RDIs or percent DVs for certain nutrients on menus and menu boards. On menus and menu boards, we are requiring the number of calories contained in standard menu items, as usually prepared and offered for sale, and a succinct statement concerning suggested daily caloric intake, as required by sections 403(q)(5)(H)(ii)(I) and (II) of the FD&C Act. The succinct statement will adequately enable the public to understand, in the context of a total daily diet, the significance of the caloric information provided on menus or menu boards. We further note that percent DVs cannot be expressed for sugar or calories because Daily Reference Values (DRVs) have not been established for these nutrients. (See § 101.9(c)(9), which lists DRVs for fat, cholesterol, sodium, and other food components.) The term Reference Daily Intake (RDI) applies to a vitamin or mineral but does not apply to calories, fat, cholesterol, sugar, or salt. (See § 101.9(c)(8)(iv), which lists the RDIs for vitamins and minerals that are essential for human nutrition.) For the Nutrition Facts Label, the amount of a nutrient is calculated as a percentage of the RDI or DRV, as appropriate, and expressed using the same term—*i.e.,* percent DV. Because ''salt'' can be either a general term applicable to substances such as calcium chloride or potassium chloride, or a synonym for the specific food substance ''sodium chloride,'' and because nutrition information generally is directed to information about the sodium content of food, we considered the request of the comment to be directed to the declaration of percent DV for ''sodium'' rather than to ''salt.''

(Comment 72) A few comments agreed with the proposed requirement (in proposed § 101.11(b)(2)(i)(A)(*1*)) that the type size for the calorie disclosure be no smaller than the name or the price of the associated standard menu item, whichever is smaller. Other comments considered that the proposed type size requirements are too prescriptive and recommended that we require only that the type size be ''clear and conspicuous.'' One comment stated that restaurants located in one State have already complied with a clear and conspicuous standard; therefore, to move to a type size no smaller than the smaller of the name or price of the menu item would require changes. Another comment asked us to provide guidance that if the calorie declaration is as large as the name, price, or description of the menu item, whichever is smaller, it is presumptively clear and conspicuous and complies with section 4205 of the ACA, rather than require a specific font size relative to the price or name; as an alternative, the type size of the calorie declaration could be the same size as the *description* of the menu item (rather than the name of the menu item) (emphasis added). One comment recommended that any required minimum type size for the calorie declaration be half the size of the name or price, whichever is smaller. Another recommended that the calorie declaration be the same size and font as either the name or price.

A few comments recommended that we require that the calorie declaration be at least as large as (or no smaller than) the name or price, whichever is larger. One comment recommended that the type size of the calorie declaration be no less than 10 point font on menus and no less than 22 point font on menu boards or a type size equal to the type size of the food listed.

(Response 72) We are retaining the type size requirements for the calorie declaration without change. We disagree that the requirements for the type size of the calorie declaration are too prescriptive. Some type size requirements suggested in the comments would be more restrictive than what we proposed. This would be true for those comments specifying a

type size at least as large as (or no smaller than) the name or price, whichever is larger; a type size the same as the type size of the name or price; a type size the same size as the description of the menu item; or a specific type size. Such type size requirements would not take into consideration the various types and sizes of menus and menu boards that may be used in covered establishments. We have concerns that a type size that is half the size of the name or price, whichever is smaller, would result in a calorie declaration that is not clear and conspicuous and, therefore, not compliant with sections 403(q)(5)(H)(ii)(I) and (II) and 403(f) of the FD&C Act. Sections 403(q)(5)(H)(ii)(I) and (II) of the FD&C Act require, in relevant part, that calorie declarations required on menus and menu boards be clear and conspicuous and clearly associated with the corresponding standard menu item. Further, section 403(f) of the FD&C Act provides that a food shall be deemed misbranded ''if any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.'' The calorie declaration specified in § 101.11(b)(2)(i)(A)(*1*) is tied to the name and price of the standard menu item, which typically are included on menus and menu boards and are two primary features of a menu or menu board typically used by consumers to make order selections. The type size requirements for calorie declarations balance the statutory requirements of sections 403(q)(5)(H)(ii)(I) and (II) and 403(f) of the FD&C Act that calorie declarations be clear and conspicuous with the mandate in section 403(q)(5)(H)(x)(II)(aa) of the FD&C Act to consider space on menus and menu boards and, thus, provide flexibility for different covered establishments.

(Comment 73) A few comments discussed the proposed requirements (in proposed § 101.11(b)(2)(i)(A)(*1*)) for the color and contrasting background of the calorie declaration. Some comments suggested changes to the proposed requirements for color and contrasting background. One comment emphasized that some menus and menu boards may have different contrasting background colors and provided two suggestions to accommodate such menus and menu boards. One suggestion was that we require that the calorie declaration have the same contrasting background, or a background at least as contrasting as the background used for the name of the associated standard menu item on the menu or menu board. As an alternative, the comment suggested that we could require that the calorie declaration have a background at least as contrasting as that used for the price and that menus using the same contrasting background as the price of the standard menu item will be presumed to comply.

One comment asserted that the color and contrast requirements are too restrictive and maintained that many menu boards have a variety of colors to enhance customer experiences. One comment suggested that the color of the calorie declaration should not be fainter or less obvious than that of the other items on the menu. Another comment asked us to permit the calorie declaration to be in the same color as the subtext that lists ingredients. One comment that opposed the proposed requirement for color asserted that ''the eye becomes overwhelmed'' when all copy is the same size and color, and the consumer misses the information or gives up looking for the information. This comment requested flexibility in color and ''weight of calorie information'' (a term the comment did not define). This comment also asked us to clarify whether ''type'' is limited to font type (*e.g.,* Arial) or whether it also includes text effects (*e.g.,* bold, italics, color).

One comment stated that the proposal was written with menu boards in mind and noted that some restaurants use translites (lighted boxes) where the name and price are in ''oversized type'' for marketing purposes. It asked us to permit the use of ''reverse type'' (which is white or light colored type printed on a dark background) and varied backgrounds if translites are used.

(Response 73) We have revised the contrasting background portion of § 101.11(b)(2)(i)(A)(*1*) to require that the number of calories be in the same contrasting background, or a background at least as contrasting as that used for the name of the associated standard menu item. We agree that this revision provides additional flexibility related to the prominence requirements to take into account that there may be different backgrounds on a single menu or menu board.

We disagree that the color requirements of the calorie declarations should be revised. Section 403(q)(5)(H)(ii) of the FD&C Act requires that the calories be disclosed in a clear and conspicuous manner and clearly associated with the standard menu item. Further, section 403(f) of the FD&C Act provides that a food shall be deemed misbranded ''if any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.'' Requiring the calorie declaration to be in the same color, or in a color at least as conspicuous as the color of the name of the associated standard menu item helps ensure that the calorie declarations are clear and conspicuous, prominently placed on the menu or menu board with such conspicuousness as compared to other words on the menu or menu board and likely to be read and understood by the ordinary individual under customary conditions of purchase and use, and clearly associated with the standard menu item. However, to match the grammatical construction of the revised requirement for the contrasting background used for the calorie declaration, we are making a conforming editorial change to require that the color used for the calorie declaration be in the same color, or a color at least as conspicuous as *that used for* the name of the associated standard menu item (emphasis added).

In addition, we are not requiring calorie declarations to be in a specific font or to include particular text effects because we recognize that menus and menu boards come in a variety of sizes and include different fonts and type sizes. We are providing flexibility by taking into consideration the space on menus and menu boards (see section 403(q)(5)(H)(x)(II)(aa) of the FD&C Act), along with the fonts and type sizes already in use by the covered establishments, while also establishing requirements that help ensure calorie declarations are disclosed in a manner that is clear and conspicuous and that otherwise satisfies the requirements of applicable sections of the FD&C Act.

We would not object to reverse type and varied backgrounds on translites, provided that the calorie declarations are clear and conspicuous and satisfy the requirements of applicable sections of the FD&C Act and § 101.11. Calorie declarations on translites would be subject to the same general requirements as disclosures on other types of menu boards, as specified in § 101.11(b)(2)(i)(A).

(Comment 74) Some comments asked us to require a comma for declaring more than 1,000 calories because consumers are accustomed to seeing a comma in numbers of one thousand or greater. The comments suggested that we revise proposed § 101.11(b)(2)(i)(A) to include a new subparagraph to state ''(*4*) Calorie numbers over 1,000 must include a comma after the thousands place.''

(Response 74) We would not object to the voluntary use of a comma for calorie declarations of 1,000 or more, but decline to revise the rule to require a comma. The requirements we have established in § 101.11(b)(2)(i)(A) adequately ensure that calorie declarations are disclosed in a clear and conspicuous manner, as required by section 403(q)(5)(H) of the FD&C Act, and render the calorie declarations likely to be read and understood by the ordinary individual under customary conditions of purchase and use, as required by section 403(f) of the FD&C Act. A covered establishment may choose to declare numbers over 1,000 with or without a comma.

(Comment 75) One comment suggested that we accommodate vision-impaired consumers by providing for alternate menus and availability of other nutrition information. This comment asserted that vision-impaired consumers suffer more from hypertension, heart problems, and diabetes.

(Response 75) We recognize that vision-impaired consumers should have access to nutrition information for standard menu items in covered establishments. However, we are only implementing the nutrition labeling requirements specified in section 403(q)(5)(H) of the FD&C Act, at this time. Covered establishments may voluntarily provide visually impaired individuals with nutrition information for standard menu items in a way that is accessible to them. For example, we would not object to a covered establishment providing nutrition information for standard menu items through a Braille menu or a menu that gives information about menu items orally, in addition to providing nutrition information in accordance with § 101.11.

XII. Additional Format Requirements That Apply When Declaring Calories on Menus and Menu Boards for Variable Menu Items, Combination Meals, and Toppings (Final § 101.11(b)(2)(i)(A)(*4*) Through (b)(2)(i)(A)(*8*))

A. Proposed Format for Declaring Calories for Variable Menu Items

Section 403(q)(5)(H)(v) of the FD&C Act requires FDA to establish by regulation standards for determining and disclosing the nutrient content for variable standard menu items that are listed as a single menu item ''through means determined by the Secretary, including ranges, averages, or other methods.'' (See the discussion of the definition of the term ''variable menu item'' in section VIII.D) In the proposed rule, we considered five options for implementing this statutory provision, and selected Option 2 (76 FR 19192 at 19207–19209). Consistent with Option 2, proposed § 101.11(b)(2)(i)(A)(*4*) would require, in relevant part, that for variable menu items, the calories must be declared as a range, in the format ''xx-yy'' where ''xx'' is the caloric content of the lowest calorie variety, flavor, or combination, and ''yy'' is the caloric content of the highest calorie variety, flavor, or combination. The other options we considered were as follows:

- *Option 1.* Single value; either in the form of an average (obtained by summing up the calorie content of all options and then dividing by the number of options) or a median of all options (obtained by determining the ''middle'' number of calories from the list of options).
- *Option 3.* Hybrid combining averages and ranges; declaration of a single average value for variable menu items whose calorie ranges fall within specified bounds and declaration of a range for variable menu items whose calorie ranges fall outside those bounds.
- *Option 4.* If only 2 options are available for an item (*e.g.,* a sandwich with fries or with fruit), provide both numbers with a forward slash between (*e.g.,* 450/350). If three or more options are available, provide the range in calories.
- *Option 5.* If only 2 options are available for an item (*e.g.,* a sandwich with fries or with fruit), provide both numbers with a forward slash between (*e.g.,* 450/350). If three or more options are available, use one of the hybrid approaches outlined in Option 3.

We also proposed specific requirements that would apply when a variable menu item appears on the menu or menu board and is a self-service food or food on display, and there is no clearly identifiable upper bound to the range, *e.g.,* all-you-can-eat buffet. In the following paragraphs, we discuss comments on these proposed provisions. After considering these comments, we have revised the provisions to:

- Require Option 4 instead of Option 2;
- Specify additional format requirements that apply when declaring calories on menus and menu boards for variable menu items, combination meals, and toppings (§ 101.11(b)(2)(i)(A)(*4*) through (b)(2)(i)(A)(*7*)); and
- Redesignate the requirements that apply to a variable menu item when there is no clearly identifiable upper bound to the range of calories to § 101.11(b)(2)(i)(A)(*8*) and clarify that such item is otherwise exempt from the requirements of § 101.11(b)(2)(i)(A) for what must be provided on menus and menu boards.

B. Decision To Require Option 4

(Comment 76) Several comments supported our proposal to require Option 2 because they considered that ranges provide more detailed information. Several comments addressed one or more of the other four options we described. One comment stated that the use of ranges does not require customers to make calculations as would be the case for medians and means. This comment asserted that declaring calories in mixed options and hybrids would be confusing because consumers would need to understand why and when a single value (*e.g.,* mean) is used rather than a range. One comment asserted that if single calorie values for each flavor and size were used rather than ranges, the menu board would be unreadable and consumers would be confused by too much information or would ignore the information. Another comment asserted that without a range, a single value calorie declaration for a variable menu item would be false.

Other comments supported the use of hybrid approaches (such as in Options 3 and 5) that would provide calorie information in both ranges and averages. One comment recommended that § 101.11(b)(2)(i)(A)(*4*) be revised to include specific exceptions that would limit the use of ranges—*i.e.,* (1) very low or no calorie beverages should be listed separately from other beverages; (2) the mean must be used for menu items that come in different flavors, varieties, or combination meals if all options are within 40 calories of each other and all of the options contain fewer than 400 calories, or if all options are within 80

calories of each other and one or more options contain more than 400 calories; and (3) if there is a fixed or default option for a combination meal, calories should be posted for that option. This comment explained that it suggested the 40-calorie range because 40 calories is used as the basis for low calorie claims, and that it suggested a cut-off of 400 calories because 400 is 20 percent of a 2,000 calorie diet and is high according to our labeling principles.

One comment recommended that a covered establishment be able to declare one range for a variable menu item that comes in different sizes only if the difference between the upper and lower limits is less than 5 percent. This comment did not explain the basis for its recommendation to use 5 percent to limit the use of ranges.

One comment stated a preference for Option 4, but also requested that we limit the use of calorie ranges, within the constraints of Option 4. This comment considered that ranges are not particularly useful to customers in putting their choices into context. Several other comments opposed Option 4 because they considered that it would be confusing.

(Response 76) After considering all five options in light of the totality of the comments and the advantages and disadvantages of each option as described in the proposed rule (76 FR 19192 at 19207 through 19209), we are requiring Option 4, rather than Option 2, as the format for declaring calories for variable menu items on menus and menu boards.

Option 4 is similar to proposed § 101.11(b)(2)(i)(A)(*4*) in that it continues to provide for the declaration of calories using a range, which some comments supported. However, Option 4 also provides for the use of a different communication tool—*i.e.,* a slash (*e.g.,* 110/230)—that is more tailored to a situation in which there are only two options available for a variable menu item. Using a slash instead of a dash (*e.g.,* 110–230) better reflects the fact that there are only two options for a variable menu item available (see the discussion in 76 FR 19192 at 19209), and more accurately informs consumers about the calories for each of the two options, whereas using a range represented by a dash is more appropriate when there are more than two options. As we discussed in the proposed rule, we recognize that in some instances, a calorie range may be so wide that a consumer may still need the calorie information for the particular menu item before he or she can make a fully informed purchase decision (76 FR 19192 at 19209). For example, the potential calorie range for a variable menu item that is offered for sale with the option of adding toppings (*e.g.,* pizza) may be very wide. We are establishing specific requirements for such variable menu items when the toppings are listed on a menu or menu board in § 101.11(b)(2)(i)(A)(*5*), in part to address the potentially large variation in calories and to provide more specific calorie information to consumers regarding their order selections.

In general, however, we agree with the comments that use of a range is less confusing than hybrids and single values where consumers may not understand how a single value is derived if a median or mean is used. Requiring a range for variable menu items where three or more options are available gives consumers a consistent format across such variable menu items and may allow covered establishments to save some space on menus and menu boards.

We disagree that we should limit the use of ranges to calorie declarations for variable menu items where the difference between the upper and lower limits is less than 5 percent. While this approach may provide for smaller range variations, such limitations likely would require additional calorie declarations on menus and menu boards and significant redesigns of menus and menu boards. Taking into consideration the space on menus and menu boards and the fact that calorie declarations for individual variable menu items will be included in the written nutrition information required under section 403(q)(5)(H)(ii)(III) of the FD&C Act and § 101.11(b)(2)(ii), we are not requiring limits on the use of ranges where the difference between the upper and lower limits is less than 5 percent, at this time. Further, the comment provided no basis to use 5 percent to limit the use of ranges.

For these reasons, we have revised § 101.11(b)(2)(i)(A)(*4*) to require Option 4 for the declaration of calories on the menu or menu board for variable menu items. Requiring the declaration of calories of each option for a variable menu by using a slash where only two options are available will reduce or limit the number of times that calories are declared as a range, as requested by some comments, while also providing specific calorie information about each option. If there are three or more options available, the calories must be provided in a range in the format ''xx–yy,'' where ''xx'' is the caloric content of the lowest calorie variety, flavor, or combination, and ''yy'' is the caloric content of the highest calorie variety, flavor, or combination. The use of a slash to declare calories for each option for a variable menu item where only two options are available and the use of a range where three or more options are available satisfy the requirements of section 403(q)(5)(H)(v) of the FD&C Act.

We have revised § 101.11(b)(2)(i)(A)(*4*) to specify, in subparagraphs (b)(2)(i)(A)(*4*) through (b)(2)(i)(A)(*7*):

- Specific requirements that apply to individual variable menu items (§ 101.11(b)(2)(i)(A)(*4*));
- Specific requirements that apply to a variable menu item that is offered for sale with the option of adding toppings listed on the menu or menu board (§ 101.11(b)(2)(i)(A)(*5*));
- Specific requirements that apply to a combination meal (§ 101.11(b)(2)(i)(A)(*6*)); and
- Specific format requirements for declaring calories for an individual variable menu item, a combination meal, and toppings as a range, if applicable (§ 101.11(b)(2)(i)(A)(*7*)).

We discuss these specific requirements in sections XII.C through XII.F.

We note that variable menu items that are self-service food or food on display are subject to the calorie declaration requirements, in § 101.11(b)(2)(iii), for food that is self-service or on display, as discussed in section XVII.B.

C. Requirements That Apply to Individual Variable Menu Items (Final § 101.11(b)(2)(i)(A)(4))

(Comment 77) One comment stated that the proposed rule suggests that a calorie range is only appropriate when a general term such as ''soda'' is used for a set of beverages, but not when specific flavors or brands are also named. The comment considered that the proposed rule therefore would require a calorie declaration for each specific size or each specific brand of a beverage listed on the menu. The comment referred to a discussion in the proposed rule (76 FR 19192 at 19216) where we compared individually listed beverages to individually listed flavors of ice cream and indicated that calorie declarations must be provided on menus and menu boards for the individually listed flavors. The comment contended that there is not enough space to list the calorie content for each size of each beverage offered for sale in the required type size. The comment also stated that this requirement will force covered establishments to refrain from listing the beverage options.

(Response 77) We are establishing in § 101.11(b)(2)(i)(A)(*4*)(*i*) through (b)(2)(i)(A)(*4*)(*iii*) requirements for

declaring calories on the menu or menu board for individual variable menu items. First, we are establishing in § 101.11(b)(2)(i)(A)(*4*)(*i*) the principle, discussed in the proposed rule, that calorie declarations must be provided on menus and menu boards for the individually listed flavors (76 FR 19192 at 19216). Section 403(q)(5)(H)(v) of the FD&C Act provides, in relevant part, that FDA shall establish by regulation standards for disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item through means determined by FDA, including ranges, averages, or other methods. Accordingly, § 101.11(b)(2)(i)(A)(*4*)(*i*) specifies that when the menu or menu board lists flavors or varieties of an entire individual variable menu item (such as soft drinks, ice cream, doughnuts, dips, and chicken that can be grilled or fried), the calories must be declared separately on the menu or menu board for each listed flavor or variety.

We acknowledge the comment's concern about space on menus and menu boards. However, a covered establishment could group together varieties or flavors that have the same number of calories (after rounding in accordance with § 101.11(b)(2)(i)(A)(*2*)) and declare the calories for that group as a single calorie declaration, specifying that the calorie declaration represents the calorie amount for each individual flavor or variety (*e.g.,* ''Diet Lemon Lime or Diet Cola (0 cal); Cola or Lemon Lime (150 cal)''). We have revised § 101.11(b)(2)(i)(A)(*4*)(*i*) to include *this option for grouping flavors and varieties that have the same calorie amounts.* We discuss in more detail the specific requirements for calorie declarations for self-service beverages in section XVII.E.3.

Flavors or varieties of variable menu items such as soft drinks, ice cream, doughnuts, dips, and chicken are not always listed on the menu or menu board. When the menu or menu board does not list flavors or varieties for an entire individual variable menu item, and only includes a general description of the variable menu item (*e.g.* ''soft drinks''), § 101.11(b)(2)(i)(A)(*4*)(*ii*) specifies that the calories must be declared for each option with a slash between the two calorie declarations where only two options are available (*e.g.,* ''150/250 calories'') or as a range in accordance with the requirements of § 101.11(b)(2)(i)(A)(*7*) where more than two options are available (*e.g.,* ''100–250 calories''). As discussed in section XII.F, § 101.11(b)(2)(i)(A)(*7*) specifies the format requirements for declaring calories as a range.

Some menus or menu boards describe flavors or varieties for only part of an individual variable menu item (such as different types of cheese offered in a sandwich). To address these types of variable menu items, § 101.11(b)(2)(i)(A)(*4*)(*iii*) specifies that when the menu or menu board describes flavors or varieties for only part of an individual variable menu item (such as different types of cheese offered in a grilled cheese sandwich (*e.g.,* ''Grilled Cheese (Cheddar or Swiss)'')), the calories must be declared for each option with a slash between the two calorie declarations where only two options are available (*e.g.,* ''450/500 calories'') or as a range in accordance with the requirements of § 101.11(b)(2)(i)(A)(*7*) where more than two options are available (*e.g.,* ''450–550 calories'').

D. Requirements That Apply to a Variable Menu Item That Is Offered for Sale With the Option of Adding Toppings Listed on the Menu or Menu Board (Final § 101.11(b)(2)(i)(A)(5))

(Comment 78) A few comments recommended that the calories either be declared as a range as proposed or be declared for the basic preparation of the item together with a separate calorie declaration for each topping. These comments supported separate calorie declarations for sauces and dressings served on the side.

One comment appeared to believe that covered establishments must list a range providing calories for pizzas with no toppings and pizzas with everything on them. The comment asserted that this calorie range would be too wide and ''useless.'' The comment also asserted that measuring toppings is not an ''exact science.'' The comment recommended that calories be disclosed on menus and menu boards for the standard build pizzas but not for toppings, because the nutrient information for the toppings would be required in the written nutrition information. However, the comment suggested that a single calorie listing for all toppings as a range from lowest to highest would be appropriate if we require calorie disclosures for pizza toppings on menus and menu boards.

One comment recommended that ranges not be the only option for pizza. The comment asserted that pizzas can have up to 34 million combinations with a range as wide as 1,610 calories. The entity submitting the comment said it had received complaints from consumers in one jurisdiction where calorie information for pizza is provided by a range and found that the customers questioned the usefulness of a wide range of calories for a whole pizza. This comment stated that some jurisdictions have attempted to address this problem by requiring that the covered establishments list calories per each component or topping. The comment asserted that listing calories for each component or topping would not be useful for pizza because each topping has a different portioning based on the size of the pizza and the total number of toppings on the pizza. The comment explained that the amount of an individual topping selection (*e.g.,* pepperoni, sausage, mushrooms, green peppers) added to a pizza is reduced based on the total number of individual toppings selections ordered. For example, a one-topping medium pizza where ham is the topping may have 10 grams of ham per slice (adding 10 calories from the ham per slice) whereas a medium pizza with ham as a topping and three other toppings may have 6 grams of ham per slice (adding 5 calories from the ham per slice). Therefore, the comment contended that individual labeling of toppings would lead to large calorie ranges that would not be useful information for the consumer. This comment stated that under one State law, pizza is a custom order and nutrition information is not required for toppings. The comment maintained that the best way to make calorie declarations for pizza is to declare calorie information for the standard build and provide calorie information for other customizations in a brochure or an online calculator.

One comment noted that, in the proposed rule, we discussed the possibility of listing calories for both the standard preparation of pizza and for each topping (76 FR 19192 at 19207) but did not codify this as we did for the written nutrition information. One comment asked us to clarify that calories should be listed for each separate pizza topping. Another comment recommended that calories for items such as pizzas and sundaes be posted for the standard preparation only if calories for each topping or option are also listed.

(Response 78) In § 101.11(b)(2)(i)(A)(*5*)(*i*) through (b)(2)(i)(A)(*5*)(*iv*), we are specifying format requirements that apply to a variable menu item that is offered for sale with the option of adding toppings listed on the menu or menu board. Doing so is consistent with section 403(q)(5)(H)(v) of the FD&C Act, responds to the comments making specific suggestions for how to declare calories for toppings such as those used

on pizza and sundaes, and acknowledges some of the unique characteristics of such toppings (*e.g.,* that the amount of each topping added to a menu item such as pizza may decrease with the total number of toppings ordered).

As noted by the comments, the proposed rule acknowledged that some comments received in response to the 2010 docket notice recommended that the calorie information for items such as pizza be displayed for the standard preparation of the item, with the standard preparation of the item clearly noted on the menu, menu board, or food tag or next to the food on display. The calorie content for each additional food component would then be displayed on the menu, menu board, food tag, or next to the food on display for each food component (76 FR 19192 at 19207). In light of these comments to the 2010 docket notice and the comments received to the proposed rule, § 101.11(b)(2)(i)(A)(*5*)(*i*) specifies that when the menu or menu board lists toppings that can be added to a menu item (such as pizza or ice cream), the calories must be declared for the basic preparation of the menu item as listed (*e.g.,* ''small pizza pie,'' or ''single scoop ice cream''). Section 101.11(b)(2)(i)(A)(*5*)(*ii*) specifies that the calories must be separately declared for each topping listed on the menu or menu board (*e.g.,* pepperoni, sausage, green peppers, onions on pizza; fudge, almonds, sprinkles on ice cream), and the menu or menu board must specify that the calories are added to the calories contained in the basic preparation of the menu item. For example:

ICE CREAM SCOOP: 300 CAL

Toppings	Added cal
Almonds	25
Fudge	50

Furthermore, a covered establishment could group toppings that have the same calorie amounts (after rounding in accordance with § 101.11(b)(2)(i)(A)(*2*)), and declare the calories for such toppings as a single calorie declaration adjacent to the toppings, specifying that the calorie declaration represents the calorie amount for each individual topping (*e.g.,* ''Red Peppers or sweet onions (adds 10 cal);'' ''Red peppers, sweet onions (adds 10 cal per topping)''). We have revised § 101.11(b)(2)(i)(A)(*5*)(*ii*) to include this option for grouping toppings that have the same calorie amounts.

We note that if the general term, ''toppings'' is used on a menu or menu board, but the individual toppings are not listed, then the format requirements of § 101.11(b)(2)(i)(A)(*4*)(*ii*) would apply (*i.e.,* the calories must be declared for each option with a slash between the two calorie declarations where only two options are available (*e.g.,* ''150/250 calories'') or as a range where more than two options are available (*e.g.,* ''100–250 calories'').

Foods such as pizza and ice cream are often offered for sale in different sizes (*e.g.,* a small, medium, or large pizza pie, and ice cream dishes that contain one, two, or three scoops of ice cream). As mentioned by a comment, the amount of a topping added to a variable menu item may vary based on the size of the variable menu item ordered by a consumer. The calorie content of each topping will likely vary accordingly, depending on the size of the variable menu item ordered. To account for the potential variability in calorie content of each topping based on the size of the variable menu item ordered, § 101.11(b)(2)(i)(A)(*5*)(*iii*) specifies that the calories for the basic preparation of the menu item must be declared for each size of the menu item, and the calories for each topping listed on the menu or menu board must either be declared separately for each size of the menu item, or declared using a slash between the two calorie declarations for each topping where only two sizes of the menu item are available (*e.g.,* ''adds 150/250 cal'') or as a range for each topping in accordance with the requirements of paragraph (b)(2)(i)(A)(*7*) of the rule where more than two sizes of the menu item are available (*e.g.,* ''adds 100–250 cal''). If a slash between two calorie declarations or a range of calorie declarations is used, the menu or menu board must indicate that the variation in calories for each topping arises from the size of the menu item to which the toppings are added. For example:

PLAIN PIZZA PIE: SMALL (12″) 500 CAL * MEDIUM (14″) 750 CAL * LARGE (16″) 1000 CAL

Toppings	Added cal		
	Small	Med	Large
Pepperoni	200	300	400
Sausage	250	350	450
Green Peppers	15	20	25

or

PLAIN PIZZA PIE: SMALL (12″) 500 CAL * MEDIUM (14″) 750 CAL * LARGE (16″) 1000 CAL

Toppings	Added cal (S/M/L pie)
Pepperoni	200–400
Sausage	250–450
Green Peppers	15–25

In the proposed rule, we requested comment on complexities that may be raised by certain variable menu items, such as those offered for sale with the option of adding toppings (such as pizza or ice cream) (76 FR 19192 at 19209). As mentioned by the comments, the amount of a topping added to a variable menu item, and therefore the calorie content of each topping, may vary not only based on the size of the menu item, but also based on the total number of toppings ordered by a consumer. Specifically, the amount of each topping added to a variable menu item may decrease as the total number of toppings ordered by a consumer increases.

Therefore, to address this complexity, we have established a specific calorie declaration requirement in § 101.11(b)(2)(i)(A)(*5*)(*iv*) for variable menu items offered for sale with the option of adding toppings listed on the menu or menu board, where the amount of the topping included on the basic preparation of the menu item decreases based on the total number of toppings ordered (such as sometimes is the case with pizza toppings). In such situation, the calories for each topping listed on the menu or menu board must be declared as single values representing the calories for each topping when added to a one-topping menu item, and the menu or menu board must specify that the calorie declaration is for the topping when added to a one-topping menu item. The following table provides an example of calorie declarations that would satisfy the requirements of § 101.11(b)(2)(i)(A)(5)(*i*) through (*iv*):

PLAIN PIZZA PIE: SMALL (12″) 500 CAL * MEDIUM (14″) 750 CAL * LARGE (16″) 1000 CAL

Toppings	Added cal (single topping S/M/L pie)
Pepperoni	200–400
Sausage	250–450
Green peppers	15–25

Structuring the requirement in this way helps ensure that consumers are given accurate and consistent information about the calories of each

topping that are added to the calories contained in the basic preparation of the menu item. We would not object if a covered establishment voluntarily includes a statement on the menu or menu board explaining how the calories per topping might fluctuate if ordering multiple toppings; for example, for a pizza pie, the statement might say, ''Calories per topping may decrease as the number of toppings per pizza increases.''

In § 101.11(b)(2)(i)(A)(*5*)(*i*) through (b)(2)(i)(A)(*5*)(i*v*), we are establishing requirements for declaring calorie information for variable menu items with toppings listed on a menu or menu board, and specifying the format and manner of such declarations, as required by sections 403(q)(5)(H)(v) and (x)(II)(bb) of the FD&C Act. Because the requirements in § 101.11 (b)(2)(i)(A)(*5*)(*iii*) and (b)(2)(i)(A)(*5*)(*iv*) address the potential variability in calorie content of each topping based on the size of the menu item, and the total number of toppings ordered, the required calorie declarations will provide accurate calorie information to consumers regarding the calorie content of each topping they order. In addition, the requirement in § 101.11(b)(2)(i)(A)(*5*)(*iii*) for toppings added to menu items that come in different sizes provides covered establishments with flexibility to choose one of two options that best fits their establishments and menus and menu boards. Allowing covered establishments to use a range for each topping to represent the added calories across various sizes of the menu item may save some space on menus and menu boards while still providing the necessary calorie information for consumers to make informed dietary choices.

We disagree that pizza with toppings generally would be a custom order for the purposes of this rule and that nutrition information is not required for such foods for a number of reasons. First, the requirements of section 403(q)(5)(H) of the FD&C Act and this rule apply to standard menu items. This rule defines a standard menu item as restaurant-type food that is routinely included on a menu or menu board or routinely offered as a self-service food or food on display. To the extent a pizza with toppings meets the definition of a standard menu item, the requirements of section 403(q)(5)(H) of the FD&C Act and § 101.11(b) would apply to such pizza.

Second, while section 403(q)(5)(H)(vii) of the FD&C Act exempts from the nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act items that are custom orders, a pizza with toppings that meets the definition of a standard menu item would not be a custom order within the meaning of § 101.11. Under the definition of ''custom order'' in § 101.11(a), a custom order is a food order that is prepared in a specific manner based on an individual consumer's request, which requires the covered establishment to deviate from its usual preparation of a menu item. For example, if a covered establishment offers a ''Meat Lovers'' pizza containing ground meat and sausage as a standard menu item, and a customer orders a ''Meat Lover's'' pizza without sausage, that order could be considered a custom order. In contrast, a pizza with toppings routinely listed on the menu or menu board of a covered establishment would meet the definition of a standard menu item, and toppings can be added to a pizza as part of the establishment's usual preparation of the menu item.

Third, pizza is explicitly identified in section 403(q)(5)(H)(v) of the FD&C Act as a variable menu item for which the nutrition information must be disclosed. If Congress had meant for pizza, including pizza with toppings, not to be covered by the requirements of section 403(q)(5)(H) of the FD&C Act, it would not have had reason to specifically include pizza as an example of the foods described in section 403(q)(5)(H)(v) of the FD&C Act.

We also disagree that calorie declarations for different toppings should not be required on menus or menu boards because these calorie declarations will be provided in the written nutrition information or can be provided in a brochure. When toppings are listed on a menu or menu board, consumers can use such information to make order selections. Accordingly, when toppings are listed on a menu or menu board, a covered establishment must declare calories for each topping on the menu or menu board in accordance with § 101.11(b)(2)(i)(A)(*5*)(*ii*) through (b)(2)(i)(A)(*5*)(i*v*). Requiring calorie declarations for toppings when they are listed on the menu or menu board helps to inform consumers' decisions by providing the calorie content of menu items before consumers make their order selections. Further, providing such information will enable consumers to make informed and healthful dietary choices.

E. Requirements That Apply to a Combination Meal (Final § 101.11(b)(2)(i)(A)(6))

(Comment 79) Some comments recommended that, when practicable, calorie amounts for all components of a variable menu item that is a combination meal be listed on the menu or menu board. One comment provided an example of a variable menu item for a pancake combination meal with a choice of bacon strips or pork sausages to accompany pancakes, eggs, and hash browns. In the comment's example, the calories for the two options ranged from 1,200 to 1,420 calories, and the comment stated that the covered establishment could list the calories as ''Two pancakes (600 calories) served with two eggs (200 calories), hash browns (300 calories) and your choice of 2 bacon strips (100 calories) or 2 pork sausages (320 calories).''

A few comments acknowledged that ranges are a better mechanism for presenting calorie information about variable menu items that are combination meals than are medians or means, but also pointed out that ranges have a disadvantage in that they do not sufficiently convey the necessary information to the consumer. One comment maintained that its consumer research shows that calorie ranges are confusing and not informative for variable menu items. Another comment recommended that if calorie ranges are used, the calories for the menu options that are included in that range must be disclosed, either on the menu, through signs for foods on display, or through the device used to provide the other written nutrition information required in section 403(q)(5)(H)(ii)(III) of the FD&C Act.

Another comment provided sample menu boards that offered for sale menu items in a meal described as ''You Pick 2'' (YP2), such as a meal consisting of a half sandwich and a half salad. For each menu item, the sample menu boards declared the number of calories in the menu item when ordered by a consumer individually and when ordered as one of the components of the ''You Pick 2'' meal, if available as a ''You Pick 2'' component (*e.g.,* ''Chicken Caesar Salad, YP2 360, Whole 720''). The comment asserted that declaring calories for each menu item individually, rather than declaring the calories for all possible combinations of its ''You Pick 2'' menu items in a range, was the best way to ensure that consumers have the necessary information to make choices about their calorie consumption.

(Response 79) We disagree that we should require calories to be listed on a menu or menu board for each component of a variable menu item that is a combination meal. In many cases, one or more components of a variable menu item (such as the pancakes, eggs,

hash browns, bacon, and pork sausages in the comment's example) are also included on a menu or menu board as standard menu items, and the calories for such components would already be on the menu or menu board when this is the case. However, we would not object if a covered establishment voluntarily lists the calories for each component of a variable menu item that is a combination meal, provided that the covered establishment also complies with the format requirements for declaring calories for variable menu items on menus and menu boards in § 101.11(b)(2)(i)(A)(*4*) through (b)(2)(i)(A)(*7*).

Section 403(q)(5)(H)(v) of the FD&C Act provides, in relevant part, that FDA shall establish standards for disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item through means determined by FDA, including ranges, averages, or other methods. Accordingly, § 101.11(b)(2)(i)(A)(*6*)(*i*) through (b)(2)(i)(A)(*6*)(*iii*) require calorie declarations for combination meals. Consistent with our selection of Option 4 for declaring calories for variable menu items generally (see discussion in section XII.B), § 101.11(b)(2)(i)(A)(*6*)(*i*) specifies that when the menu or menu board lists two options for menu items in a combination meal (*e.g.,* a sandwich with a side salad or chips), the calories must be declared for each option with a slash between the two calorie declarations (*e.g.,* ''350/450 calories''). Section 101.11(b)(2)(i)(A)(*6*)(*ii*) specifies that when the menu or menu board lists three or more options for menu items in a combination meal (*e.g.,* a sandwich with chips, a side salad, or fruit), the calories must be declared as a range in accordance with the requirements of § 101.11(b)(2)(i)(A)(*7*) (*e.g.,* ''350–500 calories'').

As such, the requirements for calorie declarations for combinations meals in § 101.11(b)(2)(i)(A)(*6*)(*i*) through (b)(2)(i)(A)(*6*)(*iii*) are consistent with the view of comments asserting that ranges are a better mechanism for presenting calorie information than are medians or means. The requirements in § 101.11(b)(2)(i)(A)(*6*)(*i*) through(b)(2)(i)(A)(*6*)(*iii*) also address the concerns of other comments that ranges do not sufficiently convey the necessary information to the consumer by limiting the use of a range to combination meals with three or more options, and providing specific calorie information about each option of a combination meal where only two options are available. In addition, we find that the small sample size (n = 127) of the consumer research submitted with one comment limits it as support for the comment's assertion that calorie ranges are confusing and not informative for variable menu items (Ref. 33). Further, although this small study suggests possible consumer preference among different declaration formats, it does not provide evidence about how consumers understand and use the formats (Ref. 33).

Immediately following, in Response 80, we discuss the third provision we are establishing in § 101.11(b)(2)(i)(A)(*6*) regarding the format of declaring calories on the menu or menu board for combination meals—*i.e.,* for ''upsize'' and ''downsize'' options for combination meals.

Regarding the ''You Pick 2'' meal described by one comment, we note that the sample menu board provided by the comment had a separate section describing an opportunity for a consumer to combine standard menu items for a special price, such as by combining any half sandwich with any half salad. The comment's sample menu board declared the number of calories for each standard menu item available for consumers to combine for a special price (*e.g.,* ''Chicken Caesar Salad, YP2 360, Whole 720''). Generally, the calories for a combination meal must be declared as a range in accordance with § 101.11(b)(2)(i)(A)(*7*) as required by § 101.11(b)(2)(i)(A)(*6*)(*ii*) if the menu or menu board lists three or more options for the menu items in the combination meal. However, in the sample menu boards provided by the comment, the section describing an opportunity for a consumer to combine standard menu items merely informed consumers of a special price when standard menu items separately listed on the menu board, each with declared calories, are combined in a ''mix and match'' situation. In this type of ''mix and match'' situation, as displayed in the sample menu board provided by the comment, a consumer would have the calorie information for each standard menu item available for the consumer to combine before he or she selects one or more standard menu items. Because the covered establishment would be providing calorie declarations for each standard menu item available for the consumer to combine on the menu or menu board that would be visible to consumers when making order selections, and taking into consideration space on menus and menu boards, we agree with the comment that requiring the disclosure of additional calorie ranges in such a situation, particularly where there are a large number of combinations available, likely would not be necessary. For these reasons, in this type of ''mix and match'' situation, where the menu or menu board describes an opportunity for a consumer to combine standard menu items for a special price (*e.g.,* ''Combine Any Sandwich with Any Soup or Any Salad for $8.99''), and the calories for each standard menu item, including each size option as described in § 101.11(b)(2)(i)(A)(*6*)(*iii*) if applicable, available for the consumer to combine are declared elsewhere on the menu or menu board, we would not require a covered establishment to also declare the calories for the combination in a range. To make this clear, § 101.11(b)(2)(i)(A)(*6*)(*iv*) of the final rule specifies that where the menu or menu board describes an opportunity for a consumer to combine standard menu items for a special price (*e.g.,* ''Combine Any Sandwich with Any Soup or Any Salad for $8.99''), and the calories for each standard menu item, including each size option as described in § 101.11(b)(2)(i)(A)(*6*)(*iii*) if applicable, available for the consumer to combine are declared elsewhere on the menu or menu board, the requirements of § 101.11(b)(2)(i)(A)(*6*)(*i*), (*ii*), and (b)(2)(i)(A)(*6*)(*iii*) do not apply.

In establishing § 101.11(b)(2)(i)(A)(*6*)(*iv*), we have considered space on menus and menu boards and how to minimize the burden on covered establishments to comply with this rule while ensuring that the requirements of section 403(q)(5)(H) of the FD&C Act and other applicable sections of the FD&C Act are satisfied and nutrition information for standard menu items is made available to consumers in a direct and accessible manner. Further, our approach to this ''mix and match'' situation is similar to our approach to a situation where a covered establishment includes packaged food (such as chips) as part of a combination meal. As discussed later in this document (see section XVII.H), a packaged food that is a food on display that bears Nutrition Facts information, including the nutrition information specified in section 403(q)(5)(H)(ii)(III) of the FD&C Act and § 101.11(b)(2)(ii) satisfies the calorie disclosure requirement for self-service food or food on display in section 403(q)(5)(H)(iii) of the FD&C Act and § 101.11(b)(2)(iii), so long as a consumer is able to examine the calorie information on the label prior to purchase.

(Comment 80) As another example of complexities that may be raised by certain variable menu items, we noted in the proposed rule that some menus with combination meals list an option to increase the size of components of those

meals for a discounted additional price (76 FR 19192 at 19209). ''Add 25 cents to Upgrade to Large Fries & Large Drink'' is an example of such an option. We stated that we were considering whether those listings should be labeled with the number or range of calories they add to the standard combination meal, and requested comment on this issue.

Several comments responded to this request for comment. In general, these comments considered that calories should be declared for each size of a menu item (such as ''upgrades'' or ''upsized options'' and ''downsized options'') offered on menus and menu boards. Some comments linked the requirement to declare calories for different sizes to different prices—*e.g.,* by considering that calories must be declared for any size option that has a distinct price on the menu or menu board. Some comments addressed combination meals, including fixed combination meals and combination meals that are variable menu items and considered that calories should be declared for fixed or variable combination meals available in multiple sizes.

(Response 80) We previously addressed comments directed to standard menu items other than variable menu items when the menu or menu board lists an option to change the size of the standard menu item (see Response 66). Here, we focus on calorie declarations for ''upsized options'' and ''downsized options'' for combination meals that are variable menu items. Consistent with our selection of Option 4 (see discussion in section XII.B), § 101.11(b)(2)(i)(A)(*6*)(*iii*) specifies that when the menu or menu board includes a choice to increase or decrease the size of a combination meal, the calorie difference must be declared for the increased or decreased size with a slash between two calorie declarations (*e.g.,* ''Adds 100/150 calories,'' ''Subtracts 100/150 calories'') if the menu or menu board lists two options for menu items in the combination meal, or as a range in accordance with the requirements of § 101.11(b)(2)(i)(A)(*7*) (*e.g.,* ''Adds 100–250 calories,'' ''Subtracts 100–250 calories'') if the menu or menu board lists three or more options for menu items in the combination meal.

For example, if a covered establishment offers for sale a combination meal that is a variable menu item consisting of a sandwich with fries or with onion rings, and the menu or menu board includes a choice to increase the size of the fries or the onion rings, the number of calories added by the larger size must be declared using a slash (*e.g.,* ''Adds 250/300 calories'') since there are only two options for menu items in the combination meal (*e.g.,* fries or onion rings).

As another example, if a covered establishment offers for sale a combination meal that is a variable menu item consisting of a sandwich with fries, onion rings, or tater tots, and the menu or menu board includes an option to increase the size of the fries, onion rings, or tater tots, the number of calories added by the larger size must be declared as a range in accordance with the requirements of § 101.11(b)(2)(i)(A)(*7*) (*e.g.,* ''Adds 250–450 calories''), because there are three options for menu items in the combination meal (*e.g.,* fries, onion rings, or tater tots).

(Comment 81) A few comments requested flexibility and recommended that the rule allow a covered establishment to choose the option for declaring calories for variable menu items that best fits its business and menu, and display calories for variable menu items in the best way, as determined by the establishment, that allows consumers to choose healthier options. One comment presented a series of specific recommendations for disclosing calories, including specific recommendations that did not fit squarely within any of the five options for disclosing calories for variable menu items discussed in the proposed rule. This comment recommended that calories for variable menu items be disclosed by (1) providing an average or range, for each size or price of the variable menu item accompanied by the term ''Avg. Cal''; (2) declaring calories for the flavors, components, or toppings that make up that variable menu item elsewhere on the primary writing; or (3) displaying the calorie amount for one preset ''build'' of the variable menu item. Under the comment's third option, the ''build'' would be representative of a finished version of the typical order and could not be a rarely ordered base product to which additional fixings are added. The comment also recommended that a covered establishment declare the calories for the additional options available for the variable menu item in a separate writing (such as an electronic kiosk, a nutrition brochure, a menu addendum, a nutrition poster, or an online nutrition application) available before or at the point of sale.

For combination meals that are fixed, this comment recommended that calories be disclosed by (1) providing total calories for the fixed combination meal or (2) providing calories for each item or component of the fixed combination meal elsewhere on the primary writing. For combination meals that contain variable menu items, the comment recommended that calories be disclosed by (1) providing calories as a range reflecting the lowest and highest total meal calorie content among the variations available; (2) providing a median or average accompanied by the term ''Avg. Cal'' if the calories for all variations within a variable combination meal are within 20 percent of the median calorie value; (3) providing calorie information for each item of the variable combination meal elsewhere on the primary writing; or (4) providing the calories for one specified variation of the variable combination meal. A covered establishment that elects to provide calories for one specified variation of the combination meal would identify the items in the variation specified, and disclose calories for the other variations of the variable combination meal in a separate writing available at the point of sale.

(Response 81) We decline the requests of these comments to allow a covered establishment to determine the method for declaring calories for variable menu items based on factors determined by the establishment. While this rule provides flexibility where appropriate, taking into account different business practices, standard menu items, and menus and menu boards, it also provides for uniform nutrition labeling requirements to be applied in covered establishments. Such consistency was one of the primary purposes of section 4205 of the ACA (see *e.g.,* section 4205(c)). Further, section 403(q)(5)(H)(v) of the FD&C Act specifically directs FDA to establish by regulation requirements for disclosing nutrition information for variable menu items through means determined by FDA. In addition, section 403(q)(5)(H)(x)(II)(bb) of the FD&C Act directs FDA to issue regulations specifying the format and manner of the nutrition information disclosure requirements of section 403(q)(5)(H) of the FD&C Act. This rule establishes requirements for disclosing the nutrition information required under section 403(q)(5)(H) of the FD&C Act while also providing flexibility. For example, we are establishing specific format requirements for calorie declarations for individual variable menu items, toppings listed on a menu or menu board, and combination meals (§ 101.11(b)(2)(i)(A)(*4*) through (b)(2)(i)(A)(*7*)), and we also are providing an exemption from the requirements for calorie declarations for combination meals in § 101.11(b)(2)(i)(A)(*6*)(*i*) through

(b)(2)(i)(A)(*6*)(*iii*) under the circumstances described in § 101.11(b)(2)(i)(A)(*6*)(*iv*). In addition, § 101.11(b)(2)(i)(A)(*3*) provides flexibility on where to place the term ''Calories'' or ''Cal'' on a menu or menu board, and § 101.11(b)(2)(i)(A)(*1*) provides flexibility for the color and contrasting background of calorie declarations. The calorie declaration requirements for variable menu items in this rule help ensure that consumers get consistent information when ordering from different covered establishments and even when ordering within a single covered establishment. For example, the approach suggested by the comments could lead to an inconsistent presentation on the same menu or menu board within a single establishment if a covered establishment determined that one approach worked best for some of its menu items and another approach worked best for other menu items.

(Comment 82) A few comments recommended that calories for combination meals be declared for the standard, ''default,'' or most popular build. As an example, one comment recommended that calories declared for a combination meal include the calories for fries if the meal is depicted on a menu board as including fries. As another example, the comment recommended that calories declared for a combination meal include the calories in a full-calorie drink if more than 50 percent of a covered establishment's combination meals are sold with a full-calorie drink. One comment considered that the standard or default is the meal depicted that accounts for more than a majority (51 percent) of the sales for that meal.

(Response 82) We disagree with the comments in part. A combination meal, including those described by the comments, could be listed on a menu or menu board as a variable menu item, meaning that it could be listed as a single menu item that comes in different flavors, varieties, or combinations. Where a combination meal is listed on a menu or menu board as a variable menu item, the meal would not have a typical ''default build'' because some components that make up the meal (*e.g.,* hamburger, fries or onion rings, soft drink) come in different flavors, varieties, or combinations that consumers are able to select. Section 403(q)(5)(H)(v) of the FD&C Act requires, in relevant part, that FDA establish by regulation standards for disclosing the nutrient content for variable menu items, through means determined by FDA, including ranges, averages, or other methods. Accordingly, we have established the requirements for calorie declarations for variable menu items that are combination meals in § 101.11(b)(2)(i)(A)(*6*)(*i*) through (b)(2)(i)(A)(*6*)(*iii*). These calorie declaration requirements communicate the variability of calorie content in the combination meal to consumers by providing the calorie information for each option when there are only two options available or in a range when there are three or more options available. In contrast, the methods for declaring calories for combination meals that are variable menu items suggested by the comments would not inform consumers that the calorie content of their order selection may vary based on the options selected in the combination meal.

Where a combination meal is not listed on a menu or menu board as a variable menu item, but is instead listed as a menu item that comes in only one flavor, variety, or combination, the combination meal would have a ''default build.'' As with a combination meal that comes in different sizes, in this situation, § 101.11(b)(2)(i)(A) requires a covered establishment to provide the number of calories contained in the combination meal listed on the menu or menu board, as usually prepared and offered for sale. (See discussion about fixed combination meals offered for sale in different sizes in Response 66.)

F. Format Requirements for Declaring Calories for an Individual Variable Menu Item, a Combination Meal, and Toppings as a Range, if Applicable (Final § 101.11(b)(2)(i)(A)(7))

As discussed previously in this document (see section XII.B), we are revising § 101.11(b)(2)(i)(A)(*4*) to require Option 4. One such revision (established in § 101.11(b)(2)(i)(A)(*7*)) specifies the format requirements that must be followed when declaring calories as a range. Under § 101.11(b)(2)(i)(A)(*7*), calories that are declared as a range must be in the format ''xx-yy,'' where ''xx'' is the caloric content of the lowest calorie variety, flavor, or combination, and ''yy'' is the caloric content of the highest calorie variety, flavor, or combination. We are establishing these specific format requirements as a separate subparagraph so that the rule does not need to include this format information each time the rule requires use of a range.

G. Exception for a Variable Menu Item When There Is No Clearly Identifiable Upper Bound to the Range of Calories (Final § 101.11(b)(2)(i)(A)(8))

Proposed § 101.11(b)(2)(i)(A)(*4*) would require, in relevant part, that if a variable menu item appears on the menu or menu board and is a self-service food or food on display, and there is no clearly identifiable upper bound to the range, *e.g.,* all-you-can-eat buffet, then the menu or menu board must include a statement, adjacent to the name or price of the item, referring customers to the self-service facility for calorie information, *e.g.,* ''See buffet for calorie declarations.'' This statement must appear in a type size no smaller than the name or price of the variable menu item, whichever is smaller, and in the same color or a color at least as conspicuous as that name or price, with the same contrasting background as that name or price.

Comments that addressed this proposed provision supported it. Therefore, we are finalizing it without change, except to:

- Redesignate it as § 101.11(b)(2)(i)(A)(*8*) and clarify that it is an ''exception'' to the requirements of § 101.11(b)(2)(i)(A) for calorie declarations that must be provided on menus and menu boards;
- Make a conforming change to § 101.11(b)(2)(i)(A) to acknowledge the exception in § 101.11(b)(2)(i)(A)(*8*);
- Provide the same flexibility for the contrasting background used for the statement referring customers to the self-service facility for calorie declarations as for the calorie declaration in § 101.11(b)(2)(i)(A)(*1*);
- Make the same conforming editorial change to the requirement directed to the color of this statement as for the calorie declaration in § 101.11(b)(2)(i)(A)(*1*);
- Make an editorial correction for clarity to insert ''the type size of'' between ''no smaller than'' and ''the name or price.''

Characterizing the provisions of § 101.11(b)(2)(i)(A)(*8*) as an ''exception'' will clarify that the requirements of § 101.11(b)(2)(i)(A)(*1*) through (b)(2)(i)(A)(*7*) do not apply when a variable menu item appears on the menu or menu board and is a self-service food or food on display, and there is no clearly identifiable upper bound to the range of calories. Providing the same flexibility for the contrasting background as for the contrasting backgrounds for calorie declarations in § 101.11(b)(2)(i)(A)(*1*) will provide a consistent approach to background requirements on menus and menu

boards. Making the conforming editorial change to the requirement directed to the color will promote consistency in terminology in the rule.

With these changes, § 101.11(b)(2)(i)(A)(*8*) specifies that if a variable menu item appears on the menu or menu board and is a self-service food or food on display, and there is no clearly identifiable upper bound to the range, *e.g.,* all-you-can-eat buffet, the menu or menu board must include a statement, adjacent to the name or price of the item, referring customers to the self-service facility for calorie information, *e.g.,* ''See buffet for calorie declarations.'' This statement must appear in a type size no smaller than the type size of the name or price of the variable menu item, whichever is smaller, and in the same color or a color at least as conspicuous as that used for that name or price, with the same contrasting background or a background at least as contrasting as that used for that name or price.

H. Declaring Calories Using Interactive Menus or New Technology

(Comment 83) In the proposed rule, we recognized that the Internet may allow for the use of different methods for disclosing calories, such as by providing a calorie tracker in the ordering frame to tally calories as customers make order selections (76 FR 19192 at 19209). We requested comment on whether different methods should be used for nutrient content declarations for interactive Internet menus in general (76 FR 19192 at 19209). One comment asked that we acknowledge the potential for advances in technology and establish a petition process to request alternative methods of nutrition information disclosure via technological innovations, *e.g.,* via smart phone applications. The comment also asked us to establish a process to approve methods that reflect technological advances that we did not anticipate but that comply with the statute.

(Response 83) We are not establishing a petition process to approve future methods for calorie declarations at this time. As suggested by the comment, we specifically acknowledged that potential technological advances may allow for the use of different methods in disclosing calories in covered establishments and requested comments on such methods. To the extent that the technological advances described by the comment provide methods for declaring calorie information in accordance with section 403(q)(5)(H) of the FD&C Act and § 101.11, such methods would be permissible. We will continue to consider whether specific advances in technology may result in alternative methods for nutrient content declarations under section 403(q)(5)(H) of the FD&C Act.

Later in this document (see Comment 113 and Response 113 in section XVI.E), we address a similar comment from the perspective of new technologies for providing written nutrition information.

XIII. Additional Requirements That Apply to Beverages That Are Not Self-Service or on Display (Final § 101.11(b)(2)(i)(A)(*9*))

(Comment 84) One comment noted that the proposed rule did not address the issue of ice fill for the declaration of calories for beverages. The comment asked us to permit covered establishments to calculate calories based on their standard ice fill as long as the level of ice fill is disclosed to consumers. The comment recommended that we expressly permit, regardless of whether there is a standard ice fill, the following statement regarding ice fill: ''Calorie content may vary based on the amount of ice used.''

(Response 84) For beverages that are standard menu items and are dispensed by an employee of a covered establishment (and, thus, are not self-service), we acknowledge that some of the beverage would be displaced by any ice added by the covered establishment. In addition, the amount of beverage displaced may vary based on the amount and type of added ice (*e.g.,* crushed, cubed, shaved). Whereas some covered establishments may dispense a standard beverage fill (*i.e.,* a fixed amount that is less than the full volume of the cup per cup size), others may not. Likewise, whereas some covered establishments may have a standard ice fill (*i.e.,* a fixed amount of ice per cup size), others may not. Accordingly, § 101.11(b)(2)(i)(A)(*9*) of the final rule requires that, for beverages that are not self-service, calories must be declared based on the full volume of the cup served without ice, unless the covered establishment ordinarily dispenses and offers for sale a standard beverage fill (*i.e.,* a fixed amount that is less than the full volume of the cup per cup size) or dispenses a standard ice fill (*i.e.,* a fixed amount of ice per cup size). If the covered establishment usually prepares and offers for sale a beverage using a standard beverage fill or dispenses a standard ice fill, the covered establishment must declare calories based on such standard beverage fill or standard ice fill. Section 101.11(b)(2)(i)(A)(*9*) of the final rule does not require a covered establishment to set a standard beverage fill or standard ice fill. Instead, § 101.11(b)(2)(i)(A)(*9*) requires the covered establishment to disclose the number of calories contained in a beverage with a standard beverage fill or ice fill ''as usually prepared and offered for sale,'' as required by section 403(q)(5)(H)(ii) of the FD&C Act. The rule also does not specify how a covered establishment should dispense a standard beverage fill or standard ice fill. A covered establishment may choose a method that is suited to its establishment—*e.g.,* by using equipment that automatically dispenses a volume specified by the establishment, by using cups that have markings that enable an employee to manually add a certain volume of beverage or ice, or by using a particular ice scoop.

Section 101.11(b)(2)(i)(A)(*9*) is consistent with section 403(q)(5)(H)(ii) of the FD&C Act, which requires covered establishments to declare on menus and menu boards the number of calories contained in standard menu items listed on such menus and menu boards, as usually prepared and offered for sale. In establishing § 101.11(b)(2)(i)(A)(*9*), we considered among other things, reasonable variations in serving sizes used by covered establishments, and therefore are allowing covered establishments to disclose calories based on the full volume of the cup served without ice, unless the covered establishment ordinarily dispenses and offers for sale a standard beverage fill or dispenses a standard ice fill. We do not expect that a statement that the calorie content of the beverage may vary based on the amount of ice used, such as the one suggested by the comment, will be necessary in light of the requirements of § 101.11(b)(2)(i)(A)(*9*).

In section XVII.D, we discuss ice fill for self-service beverages.

XIV. Comments and FDA Response on Proposed § 101.11(b)(2)(i)(B)—Succinct Statement That Must Be on Menus and Menu Boards To Provide Context About Calories in a Daily Diet

A. The Proposed Requirements

Proposed § 101.11(b)(2)(i)(B) would require the following statement designed to enable consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards: A 2,000 calorie daily diet is used as the basis for general nutrition advice; however, individual calorie needs may vary.

In the proposed rule, we referred to the statement in this provision as the ''succinct statement'' and discussed principles that should be met to help

ensure that the succinct statement is designed to enable consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards (76 FR 19192 at 19210). These principles are:

- The succinct statement should be succinct;
- The succinct statement should be in plain language that consumers can understand;
- The total caloric value should be framed appropriately so that it is not viewed as a recommendation for daily intake for every consumer;
- The succinct statement should give consumers a means to compare the calorie declaration for a menu item to total calories; and
- The succinct statement should inform consumers that individual needs vary.

In the following paragraphs, we discuss comments on this proposed provision. After considering these comments, we are:

- Revising the succinct statement; and
- Providing for an optional succinct statement (which this document refers to as the ''children's succinct statement'') for use on menus and menu boards targeted to children as a substitute for, or in addition to, the succinct statement.

B. Principles for Establishing the Succinct Statement

(Comment 85) Several comments supported the principles we discussed in the proposed rule for establishing the succinct statement.

(Response 85) We acknowledge these comments.

C. Wording of the Succinct Statement

(Comment 86) In the proposed rule, we signaled an intent to conduct consumer research to evaluate consumer response to the proposed succinct statement as well as to alternative succinct statements (which we discussed in the proposal) (76 FR 19192 at 19210). One comment supported such research, but suggested that more research should be done to assess if there is a permanent behavioral change.

(Response 86) Although the proposed rule contemplated consumer research to guide the design of the succinct statement, we are foregoing such research at this time in light of the number of comments providing useful insight regarding the proposed succinct statement, related principles, and whether we should provide a succinct statement for children.

(Comment 87) Several comments supported the proposed wording of the succinct statement. Other comments opposed the proposed wording of the succinct statement. Some comments considered that the information that calorie needs vary should not be included because it is obvious, it will clutter menus and menu boards, and there is no such phrase on packaged food. Another comment expressed concern about the use of 2,000 calories in the succinct statement and recommended that the succinct statement be better phrased to emphasize ''individual needs may vary,'' *e.g.,* by including information that many adults need fewer than 2,000 calories. This comment opposed adding phrases about the amount of exercise needed to burn a particular number of calories. One comment asserted that the proposed succinct statement is not specific enough and recommended that it focus on suggested calorie intake rather than on a typical caloric intake.

(Response 87) We are retaining the use of 2,000 calories as an appropriate reference value to include in the succinct statement. As discussed in the proposed rule, the Nutrition Facts on packaged foods uses 2,000 calories as a reference amount on which to base recommended intake for some nutrients for individuals 4 years of age and older, and the Nutrition Facts on packaged foods have been required for nearly 20 years. Moreover, a 2,000-calorie reference value is close to the midpoint of the range of energy requirements for sedentary adults (76 FR 19192 at 19209).

We also are retaining information that individual calorie needs may vary, albeit in shortened form (calorie needs vary). As discussed in the proposed rule and emphasized by the comments, although 2,000 calories is an appropriate reference value, not everyone should eat 2,000 calories per day (76 FR 19192 at 19210). As a result, a factor that FDA considered in establishing a succinct statement was whether the succinct statement should be framed appropriately so that it is not viewed as a recommendation for daily intake for every consumer because individual calorie needs vary. For these reasons, we conclude that the succinct statement should inform consumers that calorie needs vary.

(Comment 88) Several comments suggested specific revisions to the succinct statement as follows:

- ''Most adults should eat less than 2,000 calories a day, or less than 600 calories per meal.'' (A few comments cited New York State Department of Health focus groups that showed participants preferred per meal calorie messages over daily calorie messages. The comments stated that consumers could not calculate the distribution of a daily calorie budget between meals.)
- ''2,000 calories a day is an estimate of what adults need, but individual needs vary.''
- ''Consumption of 2,000 calories each day is used as the basis for general nutrition advice; however, individual daily calorie needs may be higher or lower.''
- ''The recommended caloric intake for a day varies from ____ to ____ for adolescents and adults, from ____ to ____ for school-age children, and from ____ to _____ for preschool children above age 2 years, although diets may vary.''
- ''2,000 calories a day is used for general nutrition advice, but calorie needs vary.''
- ''A 2,000 calorie daily diet is recommended for most adults; however, individual needs vary depending on age, gender, and physical activity.''
- ''To maintain a healthy diet, most adults need no more than 2,000 calories per day. Caloric needs for most children and less active adults range from 1,200 to 1,600 calories.'' One comment noted that this statement reflects a separate range for children and recommended that the statement with the range for children be on all menus, not only children's menus.

(Response 88) We have revised § 101.11(b)(2)(i)(B) to require that the following succinct statement be posted on menus and menu boards: 2,000 calories a day is used for general nutrition advice, but calorie needs vary. Most of the suggested alternatives were variations of the succinct statement we proposed. The alternative we selected captures the principles discussed in the proposed rule in a more concise fashion than the succinct statement that we proposed.

We disagree that the succinct statement should include the amount of calories per meal because individuals can choose many different ways to distribute their caloric intake throughout the day, and simply dividing the total calories into three meals does not acknowledge this variation or give consumers flexibility to distribute their own caloric intake. In addition, section 403(q)(5)(H) of the FD&C Act applies to standard menu items offered for sale in a variety of covered establishments, including establishments that do not serve foods that may constitute meals, such as chain ice cream shops and chain pretzel vendors.

We disagree that the succinct statement required on the menu or menu board should include specific reference calorie intake values or ranges for different ages or should specify the

types of factors (such as age, gender, and physical activity) that impact the caloric needs of individuals. Such details are adequately captured by the phrase ''calorie needs vary'' and would unnecessarily increase the wordiness of the statement (*i.e.,* make it less ''succinct''). Because the Nutrition Facts label on packaged foods has been required for nearly 20 years, and the Nutrition Facts uses 2,000 calories as a reference amount, consumers are already familiar with this single reference amount for daily calorie consumption for individuals 4 years of age and older. However, as discussed later in this document (see Comment 90 and Response 90), we are providing for the optional use of a children's succinct statement on a menu or menu board targeted to children as a substitute for, or in addition to, the succinct statement.

(Comment 89) One comment noted that ''a 2,000 calorie diet'' may be misleading without the terms ''daily'' or ''per day.'' The comment also recommended adding a message that calorie content alone is not the only nutritional factor to consider when choosing a diet for optimal health, because a focus on calories may incorrectly lead consumers to choose options that are nutrient poor instead of nutrient rich.

(Response 89) We agree that the succinct statement should provide the context that 2,000 calories refers to a daily diet and the succinct statement we are establishing in the final rule provides this context by informing consumers that ''2,000 calories a day is used for general nutrition advice.'' However, we disagree that the succinct statement should state that calorie content alone is not the only nutritional factor to consider. Sections 403(q)(5)(H)(ii)(I) and (II) of the FD&C Act specifically require a covered establishment to disclose the number of calories contained in standard menu items and post a ''succinct statement concerning suggested daily caloric intake'' on menus or menu boards. The succinct statement we are establishing in the final rule adequately enables consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on the menu or menu board, as required by sections 403(q)(5)(H)(ii)(I)(bb) and (II)(bb) of the FD&C Act. By allowing consumers to compare the caloric content of a standard menu item to the reference value of 2,000 calories a day, the succinct statement will enable consumers to make informed and healthful dietary choices and highlight the potential effects of additional calorie consumption throughout the day.

Further, as required by sections 403(q)(5)(H)(ii)(III) and (IV) of the FD&C Act, a covered establishment must also provide, in a written form and upon consumer request, additional nutrition information, and post on the menu or menu board a prominent, clear, and conspicuous statement regarding the availability of this additional nutrition information. Consumers therefore will have access to additional nutrition information and are notified of the availability of this information on the menu or menu board so that they are able to use the information to make informed and healthful dietary choices.

D. Succinct Statement on Menus Targeted to Children

(Comment 90) In the proposed rule, we requested comment on whether we should require a different succinct statement on menus that are targeted to children (76 FR 19192 at 19210). One comment opposed a separate succinct statement for children and a few comments recommended such a statement. One comment recommended a separate children's succinct statement if there is a separate children's menu. Another comment recommended a different succinct statement for children's menus to inform consumers that calorie needs differ because of age, sex, or activity (the comment stated that calorie needs are about 1,000 to 1,400 calories for 2- to 3-year old children, and can be up to 2,200 to 2,700 calories for 14- to 18-year old active boys).

The comments suggested the following succinct statements for children:

- ''Most children 4 to 8 years old need 1,500 calories a day, or less than 500 calories a meal.''
- ''The daily calorie requirement for children 4 to 8 years is about 1,500 calories, though individual needs vary.''
- ''Calorie needs for young children range from 1,000 to 2,000 calories per day and vary based on age and physical activity levels.''
- ''Most children 4 to 8 years old need about 1,500 calories a day including snacks, or fewer than 500 calories a meal.''

One comment suggested that we conduct consumer research on the following succinct statements:

- ''Most children 4 to 8 years old need 1,500 calories a day, or less than 500 calories a meal. Most children 2 to 3 years old need 1,200 calories a day, or less than 400 calories a meal.''
- ''Children need smaller food portions than adults. Calorie needs vary by child. For information on healthy eating, go to *www.choosemyplate.gov.''*
- ''Children's calorie needs vary by age and the individual child's nutrition and health status. Please consult your child's physician or health care professional.''

(Response 90) We have revised § 101.11(b)(2)(i)(B) to provide for the optional use of either of the following children's succinct statements on menus and menu boards targeted to children as a substitute for, or in addition to, the succinct statement:

- 1,200 to 1,400 calories a day is used for general nutrition advice for children ages 4 to 8 years, but calorie needs vary.
- 1,200 to 1,400 calories a day is used for general nutrition advice for children ages 4 to 8 years and 1,400 to 2,000 calories a day for children 9 to 13 years, but calorie needs vary.

Under § 101.11(b)(2)(i)(B), a covered establishment may use one of these children's succinct statements on a menu or menu board targeted to children (*e.g.,* on a standalone children's menu or menu board, or in the children's section of a general menu or menu board) as a substitute for, or in addition to, the succinct statement required in § 101.11(b)(2)(i)(B). To ensure consistency, a covered establishment that includes a children's succinct statement on a menu or menu board may only use the children's succinct statements listed in § 101.11(b)(2)(i)(B). If the covered establishment chooses not to use the children's succinct statements listed in § 101.11(b)(2)(i)(B), it must use the succinct statement required in § 101.11(b)(2)(i)(B).

We realize that many covered establishments offer food selections that may only be purchased for children under a certain age specified by the covered establishment (*e.g.,* under 9 years). Some of these children's food selections are offered on separate children's menus, while others are included on the general menu or menu board along with items for all consumers. We have concluded that covered establishments should have the option of providing a succinct statement more relevant to children on menus and menu boards that provide food selections targeted to children. Childhood obesity is an important public health concern, and a succinct statement specifically targeted to the calorie needs of children may enable parents and children to make informed dietary choices.

We considered whether covered establishments should be required to provide both the 2,000-calorie succinct statement and an additional children's succinct statement on menus and menu boards. Sections 403(q)(5)(H)(ii)(I)(bb)

and (II)(bb) of the FD&C Act require that covered establishments post on menus and menu boards ''*a succinct statement* concerning suggested daily caloric intake . . . designed to enable the public to understand, in the context of a total daily diet, the significance of the [calorie] information'' provided on menus and menu boards. (Emphasis added.) Therefore, it is reasonable to interpret these sections to only require one succinct statement on menus and menu boards, and we are providing for the optional use by a covered establishment of a children's succinct statement on menus or menu boards targeted to children. Accordingly, the rule does not require that a covered establishment that includes a children's succinct statement on a menu or menu board targeted to children also include the succinct statement required by § 101.11(b)(2)(i)(B) on that menu or menu board.

To develop the children's succinct statement, we used the 2010 Dietary Guidelines as the reference for the estimated calorie needs of children (Ref. 3). The 2010 Dietary Guidelines are based on the review of scientific evidence by a committee of scientific experts. The 2010 Dietary Guidelines provide information and advice for choosing a healthy eating pattern that focuses on nutrient-dense foods and beverages, and that contributes to achieving and maintaining a healthy weight. One goal of the 2010 Dietary Guidelines is to aid policymakers in designing and carrying out nutrition-related programs. As such, the 2010 Dietary Guidelines are well suited to serve as the reference for the estimated calorie needs of children for the purpose of this rule.

As the comments noted, there is broad variability in the daily caloric needs of children, and this variability is captured in table 2–3 in the 2010 Dietary Guidelines. Table 2–3 reports the estimated calorie needs per day by age, gender, and physical activity level. The relevant data and information in table 2–3, which we used to develop the children's succinct statement, covers four age groups (ages 2 to 3 years, 4 to 8 years, 9 to 13 years, and 14 to 18 years) and three activity levels (sedentary, moderately active, and active). Male and female children are grouped together in the group aged 2 to 3 years but reported separately in the groups aged 4 to 8 years, 9 to 13 years, and 14 to 18 years. Although most comments suggesting specific wording for the children's succinct statement focused on the calorie needs of children ages 8 and younger, some covered establishments may offer food selections targeted to somewhat older children—*e.g.,* for ''kids under 12.'' Therefore, we focused on estimated caloric needs for children aged 4 to 8 and children aged 9 to 13. We did not focus on the estimated caloric needs for the youngest age group (aged 2 to 3 years) and the oldest age group (aged 14 to 18 years). Although one comment suggested that we include the youngest age group (aged 2 to 3 years), we considered a number of factors and ultimately decided not to include the youngest age group (aged 2 to 3 years) and the oldest age group (aged 14 to 18 years). First, we considered space on menus and menu boards, the types of standard menu items offered in covered establishments, and different practices among covered establishments. Second, we were concerned that a children's succinct statement with four age groups would cross a reasonable threshold for one of the principles governing the succinct statement—*i.e.,* that it be succinct. Third, we concluded that covered establishments might be deterred from voluntarily posting a children's succinct statement on menus and menu boards if such statement was not succinct. Fourth, children's menus are typically not targeted to the youngest and the oldest age groups.

In developing the specific language of the two options for the children's succinct statement, we considered the principles that apply to the succinct statement, the comments, data and information discussed in the proposed rule, and the wording established in § 101.11(b)(2)(i)(B) for the succinct statement. As with the succinct statement, we concluded that the children's succinct statement should be directed to an estimated daily caloric need rather than the amount of calories per meal.

In contrast to the succinct statement, which uses a single reference value (2,000 calories) regardless of age group, we concluded that the children's succinct statement needed to both reflect a range of calories and link that range of calories to a specific age group to adequately enable parents and possibly some children to understand the significance of the calorie information in the context of their total daily diet. We focused on estimated caloric needs for sedentary children and did not focus on additional calories consumed by active children. This is consistent with our approach to the succinct statement, where the 2,000 calorie daily diet does not take into account additional calories consumed by persons such as athletes or persons with a regular fitness regime. As with the succinct statement, the children's succinct statement addresses the differential caloric consumption associated with activity and other factors by informing consumers that ''calorie needs vary.''

Table 2–3 in the 2010 Dietary Guidelines reports the same estimated daily caloric needs for sedentary males and females aged 4 to 8 years (*i.e.,* 1,200 to 1,400 calories) and, thus, we selected 1,200 to 1,400 calories as the range to include for children aged 4 to 8 years in each of the two options listed in § 101.11(b)(2)(i)(B) for the children's succinct statements. Table 2–3 in the 2010 Dietary Guidelines reports different estimated daily caloric needs for sedentary males aged 9 to 13 years (*i.e.,* 1,600 to 2,000 calories) and sedentary females aged 9 to 13 years (*i.e.,* 1,400 to 1,600 calories). For the option listed in § 101.11(b)(2)(i)(B) for a children's succinct statement that includes the estimated caloric needs of children aged 9 to 13 years, we simply reported the range as the lowest estimated caloric needs for sedentary males and females aged 9 to 13 years (*i.e.,* 1,400 calories for females) and the highest estimated caloric needs for sedentary males and females aged 9 to 13 years (*i.e.,* 2,000 calories for males). Thus, the listed option that includes the group aged 9 to 13 years reports the range of estimated caloric needs as 1,400 to 2,000 calories.

(Comment 91) One comment suggested that children's menus may benefit from a traffic light concept (*e.g.,* green, yellow, and red signage) that indicates which foods should be eaten more or less frequently.

(Response 91) Section 403(q)(5)(H) of the FD&C Act generally requires covered establishments to provide calorie declarations for standard menu items on menus, menu boards, and signs adjacent to self-service food and food on display, and other nutrition information in a written form. Section 403(q)(5)(H) also requires covered establishments to post on menus and menu boards a succinct statement concerning daily caloric intake and a statement regarding the availability of the written nutrition information. FDA is establishing requirements to implement only what is specified in section 403(q)(5)(H) of the FD&C Act and information that is necessary for the efficient enforcement of such requirements.

E. Requirements for the Succinct Statement To Be Prominent, Clear, and Conspicuous

Proposed § 101.11(b)(i)(2)(B)(*1*) would require that the succinct statement be posted prominently and in a clear and conspicuous manner in a type size no

smaller than the smallest calorie declaration appearing on the same menu or menu board and in the same color or in a color at least as conspicuous as the calorie declarations and with the same contrasting background as the calorie declarations. In the proposed rule, we recognized that some restaurants and similar retail food establishments may have menu boards that list very few items in very large font. We asked for comment on whether the succinct statement and statement of availability should be tied to the type size for some menus that have few items and that may be listed in large type size (76 FR 19192 at 19211).

In the following paragraphs, we discuss comments on this proposed provision. After considering these comments, we are:

- Revising the proposed provision to provide additional flexibility for the contrasting background of the succinct statement;
- Making a conforming editorial change to the requirement for the color used for the succinct statement for grammatical consistency; and
- Making an editorial correction for clarity to insert ''the type size of'' between ''no smaller than'' and ''the smallest calorie declaration.''

(Comment 92) One comment suggested that the size of the succinct statement be ''no smaller than the menu description or what any ordinary person can read without any trouble.'' Due to space limitations on menus, this comment considered that the succinct statement should not be tied to the type size on menus that list relatively few items that are listed in very large type size. One comment asked us to permit a type size smaller than the smallest calorie declaration appearing on the menu or menu board due to the limited space on menu boards and the amount of text required to be included in the statement. Another comment maintained that the succinct statement takes up too much space and would force covered establishments to decrease the type size used for calories. A few comments suggested that we require the succinct statement to be no smaller than the type size most frequently used throughout the menu and in the same color and contrast, or in color and contrast at least as conspicuous and contrasting as the color and contrast most frequently used throughout the menu for the names of standard menu items.

(Response 92) We agree, in part, and disagree, in part, with these comments. As a practical matter, the type size of the succinct statement would, as requested by the comments, likely be no smaller than the menu description or what any ordinary person can read without any trouble, because § 101.11(b)(2)(i)(B)(*1*) requires that the type size for the succinct statement be no smaller than the smallest type size of any calorie declaration and, under § 101.11(b)(2)(i)(A)(*1*), the type size of the calorie declaration would be in a type size no smaller than the type size of the name or the price of the associated standard menu item, whichever is smaller. Because consumers typically view the name and/or price of a standard menu item to place an order, our decision to anchor the type size of the succinct statement to the type size of information already on the menu or menu board acts, in essence, as an objective and measurable performance standard and helps ensure, among other things, that the succinct statement will be clear and conspicuous to consumers and posted prominently, as required by sections 403(q)(5)(H)(ii) and 403(f) of the FD&C Act.

We disagree that the type size, color, and contrast should be tied to the type size, color, and contrast most frequently used throughout the menu. Section 101.11(b)(2)(i)(A)(*1*) provides flexibility for the type size, color, and contrasting background used for the calorie declaration (and, accordingly, § 101.11(b)(2)(i)(B)(*1*) provides flexibility for the type size, color, and contrasting background used for the succinct statement), by anchoring these three parameters to the name or price of standard menu items. The suggestion in this comment would establish an additional burden for a covered establishment, particularly when a covered establishment has more than one menu or menu board, to determine the type size most frequently used. The comment provided no basis, such as apparent benefit for either the restaurant or the consumer, to justify this additional burden.

However, we agree that we should provide additional flexibility for the contrasting background of the succinct statement by permitting the statement to be in a background at least as contrasting as that used for the calorie declarations. Consequently, we have revised § 101.11(b)(2)(i)(B)(*1*) to do so. We also are making a conforming editorial change to the grammatical construction of the requirement for the color used for the succinct statement to match the grammatical construction of the revised requirement for the contrasting background used for the succinct statement. With these changes, § 101.11(b)(2)(i)(B)(*1*) requires that the succinct statement be posted prominently and in a clear and conspicuous manner in a type size no smaller than the smallest *type size of any* calorie declaration appearing on the same menu or menu board and in the same color or in a color at least as conspicuous as *that used for* the calorie declarations, and with the same contrasting background *or a background at least as contrasting as that used for* the calorie declarations (emphasis added).

F. Placement of the Succinct Statement on Menus and Menu Boards

For menus, proposed § 101.11(b)(2)(i)(B)(*2*) would require that the succinct statement appear on the bottom of each page of the menu. On menu pages that also bear the statement regarding the availability of the written nutrition information required in § 101.11(b)(2)(i)(C), proposed § 101.11(b)(2)(i)(B)(*2*) also would require that the succinct statement appear directly above the statement of availability required in § 101.11(b)(2)(i)(C). For menu boards, proposed § 101.11(b)(2)(i)(B)(*3*) would require that the succinct statement appear on the bottom of the menu board, immediately above the statement of availability required in § 101.11(b)(2)(i)(C).

In the following paragraphs, we discuss comments on these proposed provisions. After considering these comments, we have revised the proposed provisions for placement of the succinct statement to provide additional flexibility for the succinct statement to appear immediately above, below, or beside the statement of availability of the written nutrition information.

(Comment 93) Several comments agreed with the proposed placement requirements for the succinct statement. One comment recommended that covered establishments be permitted to put the succinct statement on a separate sign near the menu boards because of space constraints.

(Response 93) We are not revising the rule to allow a covered establishment to post the succinct statement on a separate sign near a menu board as suggested by the comment. First, we are concerned that if a covered establishment were to post the succinct statement on a separate sign, the statement would not be posted prominently, and therefore, consumers would not be able to use the statement to understand, in the context of a total daily diet, the significance of the calorie information that is provided on the menu board. Second, this rule provides flexibility regarding posting calorie declarations and other information on

menus and menu boards, including flexibility regarding the size of the calorie declarations and placement of the statement of availability of additional written nutrition information, such that covered establishments have a number of ways to satisfy the requirements based on their menus and menu boards and business operations. Lastly, sections 403(q)(5)(H)(ii)(I)(bb) and (II)(bb) of the FD&C Act require that covered establishments post the succinct statement on menus and menu boards prominently and in a clear and conspicuous manner. The comment's request would be inconsistent with the express requirements of sections 403(q)(5)(H)(ii)(I)(bb) and (II)(bb) of the FD&C Act. Later in this document, we discuss the requirements for placement of the succinct statement on small signs for self-service food and food on display that may meet the definition of a ''menu'' or ''menu board'' in section 403(q)(5)(H)(xi) of the FD&C Act, in that such signs are the primary writings of the establishment from which consumers make order selections (see the discussion of § 101.11(b)(2)(iii)(B) in section XVII.G).

(Comment 94) A few comments expressed concern about the space that the succinct statement would take on menus and the proposed requirement that the statement appear on every page, in light of other statements on menus (such as the advisory statements in our Food Code, footnotes regarding daily availability of various menu items, and footnotes referencing ''net weight before cooking''). The comments asserted that menus would become cluttered. One comment asserted that the message we want to convey would ''get lost in the noise at the bottom of each page.'' The comments agreed that the succinct statement should appear at the bottom of menus and menu boards, but asked us to clarify that it would appear only once on each menu or menu board and not on each page or panel. The comments recommended that for menus, the succinct statement must appear either on the first or last page. One comment suggested that the succinct statement need only appear on one panel of the main menu board that is visible at all times to consumers.

One comment asserted that because space is finite, adding the required succinct statement to multiple pages of a menu would lead to removal of ''optional information,'' such as some menu offerings. This comment expressed concern that menu items, such as seafood dishes, will be dropped from menus to make room for this additional information to appear on each page of the menu. The comment noted that the 2010 Dietary Guidelines have outlined the importance of including seafood in a healthy diet, and that roughly 67 percent of the seafood consumed in the United States is consumed away from the home.

(Response 94) We disagree that the succinct statement needs to appear only once on menus. In particular, we are concerned that for large multi-paged menus, consumers may not read the entire menu and instead may turn to a specific section of the menu (*e.g.,* the section for burgers and sandwiches). Unless the succinct statement is on the page for that particular section, it is possible that consumers could miss the succinct statement and therefore be unable to use the statement ''to understand, in the context of a daily diet, the significance of the caloric information that is provided on the menu,'' as specified by section 403(q)(5)(H)(I)(bb) of the FD&C Act. Therefore, in § 101.11(b)(2)(i)(B)(*2*), we are requiring the succinct statement to appear on the bottom of each page of the menu.

However, we agree that the succinct statement needs to appear only once on a menu board, including a menu board consisting of more than one panel in one physical location (a multi-paneled menu board). For the purpose of this rule, we consider such a multi-paneled menu board to be a single menu board, provided that the entire multi-paneled menu board is visible to consumers when consumers are placing order selections for the standard menu items listed on such menu board. A multi-paneled menu board is different from a menu with multiple pages because all panels are visible to consumers when they place an order, regardless of the specific panel containing the menu item the consumer selects. A succinct statement on a single panel of a multi-paneled board is likely to be clear and conspicuous to the consumer and posted prominently, provided that the type size, color, and background of the succinct statement meet the applicable requirements in § 101.11(b)(2)(i)(B)(*1*) and the entire multi-paneled menu board is visible to consumers when consumers are placing order selections for the standard menu items listed on such menu board.

Regarding one comment's assertion that requiring the succinct statement to appear on each page of a menu could lead to the removal from a menu or menu board of information that a covered establishment views as optional, we note that a decision to remove ''optional information'' or to drop certain menu items from menus belongs to the covered establishment. The succinct statement is necessary on the bottom of each page of a menu that includes standard menu items and calorie information because the succinct statement is designed to enable consumers ''to understand, in the context of a total daily diet, the significance of the caloric information that is provided on the menu,'' as required by section 403(q)(5)(H)(I)(bb) of the FD&C Act. However, we have also considered the space on menus and therefore provided flexibility where appropriate. For example, in addressing comments on the statement of availability of written nutrition information, we concluded that this statement of availability need appear only once on a menu or menu board. In reaching that conclusion, we considered the goals of the succinct statement and the statement of availability, which are different (see the discussion of § 101.11(b)(2)(i)(C) in section XV.C).

(Comment 95) A few comments maintained that the proposed order of the succinct statement (*i.e.,* in relation to the statement of availability of additional written nutrition information) limits flexibility. The comments asserted that both statements could be just as clear and conspicuous if they were placed in some other way.

(Response 95) We agree with the comments, and are providing flexibility for the placement of the succinct statement in relation to the statement of availability of the written nutrition information. Consequently, we have revised § 101.11(b)(2)(i)(B)(*2*) and (b)(2)(i)(B)(*3*) to provide that on menu pages that also bear the statement of availability and on menu boards, the succinct statement must appear immediately above, below, or beside the statement of availability. In addition, as an editorial change for consistency throughout § 101.11, we have revised the cross-references within § 101.11(b)(2)(i)(B)(*2*) and (b)(2)(i)(B)(*3*) referring to the statement of availability to read ''the statement required by paragraph (b)(2)(i)(C) of this section'' (*i.e.,* § 101.11(b)(2)(i)(C)). With these changes, § 101.11(b)(2)(i)(B)(*2*) requires that for menus, the succinct statement must appear on the bottom of each page of the menu. On menu pages that also bear the statement required by § 101.11(b)(2)(i)(C), the succinct statement must appear immediately above, below, or beside the statement required by § 101.11(b)(2)(i)(C). In addition, with these changes § 101.11(b)(2)(i)(B)(*3*) requires that for menu boards, the succinct statement must appear on the bottom of the menu board, immediately above, below, or

beside the statement required by § 101.11(b)(2)(i)(C).

XV. Comments and FDA Response on Proposed § 101.11(b)(2)(i)(C)—Statement That Must Be on Menus and Menu Boards About Availability of Written Nutrition Information

A. Proposed Wording of the Statement of Availability

Proposed § 101.11(b)(2)(i)(C) would require the following statement regarding the availability of the additional written nutrition information required in § 101.11(b)(3)(i) on all forms of the menu or menu board: Additional nutrition information available upon request. In a correction document, we corrected the regulatory designation of the requirement for the statement of availability to be § 101.11(b)(2)(ii) rather than § 101.11(b)(3)(i) (76 FR 30050 at 30051).

One comment supported the wording of the statement of availability and no comments opposed the wording. We are finalizing the proposed wording of the statement of availability without change.

B. Requirements for the Statement of Availability To Be Prominent and Conspicuous

Proposed § 101.11(b)(2)(i)(C)(*1*) would require that the statement of availability be posted prominently and in a clear and conspicuous manner in a type size no smaller than the smallest calorie declaration appearing on the same menu or menu board and in the same color or in a color at least as conspicuous as the caloric declarations, and with the same contrasting background as the caloric declarations.

In the following paragraphs, we discuss comments on this proposed provision. After considering these comments, we are:

- Revising the proposed provision to provide additional flexibility for the contrasting background used for the statement of availability;
- Making a conforming editorial change to the requirement for the color used for the statement of availability for grammatical consistency; and
- Making an editorial correction for clarity to insert ''type size of any'' between ''no smaller than the smallest'' and ''calorie declaration.''

(Comment 96) One comment recommended that the type size of the statement of availability ''be no smaller than the menu description or what any ordinary person can read without any trouble.'' Some comments recommended that we permit a smaller type size for the statement of availability. A few comments suggested that we require the statement of availability to be in a type size no smaller than the type size most frequently used throughout the menu. Some comments suggested that the statement of availability be in the same color or a color at least as conspicuous as the color most frequently used throughout the menu for the names of standard menu items and with the same contrasting background or a contrasting background at least as contrasting as the background most frequently used throughout the menu for the names of standard menu items.

(Response 96) These comments on the proposed requirements for type size, color, and contrasting background of the statement of availability are analogous to certain comments on the proposed requirements for the succinct statement (see Comment 92), and our response to these comments is analogous to our response to Comment 92 (see Response 92). Specifically, we disagree that a smaller type size should be used for the statement of availability for the reasons discussed in Response 92. We disagree that the type size, color, and contrasting background of the statement of availability should be tied to the type size, color, and contrasting background most frequently used throughout the menu for the names of standard menu items for the reasons discussed in Response 92. However, we agree that we should provide additional flexibility for the contrasting background of the statement of availability by permitting the statement to be in a background at least as contrasting as that used for the calorie declarations. Consequently, we have revised § 101.11(b)(2)(i)(C)(*1*) to do so. In addition, we are making a conforming editorial change to the grammatical construction of the requirement used for the color of the statement of availability to match the grammatical construction of the revised requirement for the contrasting background used for the statement of availability. We also are making an editorial correction for clarity to insert ''type size of any'' between ''no smaller than the smallest'' and ''calorie declaration.'' With these changes, § 101.11(b)(2)(i)(C)(*1*) requires that the statement of availability be posted prominently and in a clear and conspicuous manner in a type size no smaller than the smallest *type size of any* calorie declaration appearing on the same menu or menu board and in the same color or in a color at least as conspicuous as *that used for* the caloric declarations, and with the same contrasting background *or a background at least as contrasting as that used for* the caloric declarations. (Emphasis added.) We conclude that the type size, color, and contrasting background requirements for the statement of availability in § 101.11(b)(2)(i)(C)(*1*) will help ensure that the statement of availability is prominent, clear, and conspicuous, as required by sections 403(q)(5)(H)(ii)(IV) and 403(f) of the FD&C Act.

C. Placement of the Statement of Availability

For menus, proposed § 101.11(b)(2)(i)(C)(*2*) would require that the statement of availability appear on the bottom of the first page with menu items. For menus with more than two pages, it would also require that the statement of availability appear either at the bottom of every page with menu items (proposed § 101.11(b)(2)(i)(C)(*2*)(*i*)), or at the bottom of only the first page with menu items, as long as a symbol (*e.g.,* asterisk) clearly referring to the required statement appearing on the first page of the menu follows the term 'Calories' or 'Cal,' where the term first appears on each page after the page with the statement (proposed § 101.11(b)(2)(i)(C)(*2*)(*ii*)). For menu boards, proposed § 101.11(b)(2)(i)(C)(*3*) would require that the statement of availability appear on the bottom of the menu board immediately above or below the succinct statement. In the following paragraphs, we discuss comments on these proposed provisions. After considering these comments, we are:

- Revising proposed § 101.11(b)(2)(i)(C)(*2*) to require that the statement of availability appear on the first page of a menu with menu items and to delete the proposed provisions that would have required the statement of availability, or a symbol referring to the statement of availability, on subsequent menu pages;
- Revising both proposed § 101.11(b)(2)(i)(C)(*2*) and (b)(2)(i)(C)(*3*) to provide that the statement of availability must appear immediately above, below, or beside the succinct statement; and
- Making additional editorial changes for consistency.

(Comment 97) Some comments supported the proposed requirements for placement of the statement of availability. A few comments disagreed with our proposal that a symbol (*e.g.,* asterisk) can be used to refer to the statement of availability on the first page, if the statement does not appear on every page. These comments considered that requiring the placement

of asterisks on each subsequent page in reference to a disclosure on the first page with menu items would only confuse a reader who, upon seeing an asterisk, has been trained since elementary school to look for the associated footnote at the bottom of the page on which the asterisk appears.

A few comments expressed concern about the space that the statement of availability would take in light of other statements on menus (such as consumer advisories), and recommended that the statement of availability appear only once on the menu, either on the first or last page. The comments agreed that the statement of availability should appear at the bottom of menus and menu boards, but recommended that we require that the statement appear only once on menus and menu boards, and not on each page or panel. One comment recommended that covered establishments be able to put the statement of availability on a separate sign near the menu boards.

(Response 97) We are not revising the rule to allow a covered establishment to post the statement of availability on a separate sign near a menu board as suggested by the comment. This comment is analogous to a comment on the proposed requirements for the placement of the succinct statement (see Comment 93), and our response to this comment is analogous to our response to Comment 93 (see Response 93). Section 403(q)(5)(H)(ii)(IV) of the FD&C Act requires that covered establishments post a prominent, clear, and conspicuous statement of availability on menus and menu boards. The comment's request is inconsistent with the express statutory direction. Later in this document, we discuss the requirements for placement of the statement of availability on small signs for self-service food and food on display that may meet the definition of a ''menu'' or ''menu board'' in section 403(q)(5)(H)(xi) of the FD&C Act, in that such signs are the primary writings of the establishment from which consumers make order selections (see the discussion of § 101.11(b)(2)(iii)(B) in section XVII.G).

We agree that an asterisk referring to a statement on the first page of a menu may confuse consumers. We also agree that the statement of availability only needs to appear on one page of a menu. Unlike the succinct statement, which is designed to enable the public to understand the significance of the caloric information in the context of a total daily diet and is therefore needed on each page of a menu that includes standard menu items and calorie information, the statement of availability informs consumers that there is additional written nutrition information available on the premises of the covered establishment upon request. We believe that posting the statement of availability on one page of a menu will be adequate to achieve that goal. Consequently, we have revised § 101.11(b)(2)(i)(C)(*2*) to require that the statement of availability appear on the first page of a menu with menu items and to delete the proposed provisions that would have required the statement of availability, or an asterisk referring to the statement of availability, on subsequent menu pages.

(Comment 98) A few comments maintained that the proposed order of the statement of availability in relation to the succinct statement limits flexibility. The comments contended that both statements would be just as clear and conspicuous if they were to appear in some other position such as side by side or in some other place on the page.

(Response 98) For menu boards, we note that there was an inconsistency in the proposed rule between the preamble and the codified regarding the proposed order of the statement of availability in relation to the succinct statement. According to the preamble, the statement of availability would have been required to appear immediately below the succinct statement (76 FR 19192 at 19211), while in the codified text, proposed § 101.11(b)(2)(i)(C)(*3*) would require that the statement of availability appear on the bottom of the menu board immediately above or below the succinct statement. For both menus and menu boards, we agree with the comments and are providing additional flexibility for the placement of the statement of availability of the written nutrition information in relation to the succinct statement. We have revised proposed § 101.11(b)(2)(i)(C)(*2*) and (b)(2)(i)(C)(*3*) to provide that for menus and menu boards, the statement of availability must appear immediately above, below, or beside the succinct statement. For clarity and consistency, we are specifying the placement of the statement of availability in § 101.11(b)(2)(i)(C)(*2*) in relation to the succinct statement even though proposed § 101.11(b)(2)(i)(C)(*2*) did not do so.

XVI. Comments and FDA Response on Proposed § 101.11(b)(2)(ii)—Nutrition Information That Must Be Made Available in Written Form

A. Required Nutrients

Proposed § 101.11(b)(2)(ii) would require, in relevant part, that:

- Certain nutrition information for a standard menu item be available in written form on the premises of the restaurant or similar retail food establishment and provided to the customer upon request;
- The nutrition information be presented in the order listed and using the measurements listed, except as provided in § 101.11(b)(2)(ii)(B);
- Rounding of these nutrients be in compliance with § 101.9(c); and
- Covered establishments include the following nutrition information in the written form, as specified in § 101.11(b)(2)(ii)(A)(*1*) through (b)(2)(ii)(A)(*11*):

1. Total number of calories derived from any source (cal)
2. Total number of calories derived from the total fat (fat cal)
3. Total fat (g)
4. Saturated fat (g)
5. *Trans* fat (g)
6. Cholesterol (mg)
7. Sodium (mg)
8. Total carbohydrate (g)
9. Dietary fiber (g)
10. Sugars (g)
11. Protein (g)

In the following paragraphs, we discuss comments on this proposed provision. After considering these comments, we have revised the provision to:

- Replace the terms ''total number of calories derived from any source'' and ''total number of calories derived from the total fat'' with the terms ''total calories'' and ''calories from fat'';
- Provide that covered establishments may use the abbreviations allowed for Nutrition Facts for certain packaged foods in § 101.9(j)(13)(ii)(B); and
- Clarify that the information must be provided on the premises of the ''covered establishment'' rather than the ''restaurant or similar retail food establishment'' (see the discussion in section VI.I).

(Comment 99) One comment suggested that we come up with a standard list of abbreviations for the nutrients for consistency and consumer understanding. This comment pointed out that we proposed ''Cal'' as an abbreviation for calories but did not suggest abbreviations for the other nutrients.

(Response 99) We agree with this comment. Providing abbreviations for the written nutrition information will improve the consistency of the written nutrition information provided by different covered establishments. Therefore, we have revised § 101.11(b)(2)(ii) to provide that covered establishments may use the abbreviations allowed for Nutrition

Facts for certain packaged foods in § 101.9(j)(13)(ii)(B) for the nutrient information required to be disclosed in the written nutrition information under section 403(q)(5)(H)(ii)(III) of the FD&C Act. For example, a covered establishment may use ''sat fat'' for saturated fat and ''cholest'' for cholesterol.

(Comment 100) One comment suggested that ''total number of calories derived from any source'' (required under section 403(q)(1)(C) of the FD&C Act) be changed to ''total number of calories,'' which, according to the comment, is clear and concise.

(Response 100) We agree with the comment's suggestion that the term ''total number of calories derived from any source'' can be revised to be more concise. Specifically, we are replacing the term ''total number of calories derived from any source'' (which had been specified by section 403(q)(1)(C) of the FD&C Act) with ''total calories.'' This change is consistent with how the ''total number of calories derived from any source'' is disclosed in the Nutrition Facts under § 101.9. For consistency, we are making an analogous revision to replace the term ''total number of calories derived from the total fat'' with ''calories from fat.'' This change is consistent with section 403(q)(1)(C) of the FD&C Act, and the declaration of ''total calories'' and ''calories from fat'' will be consistent with the terms used for nutrition labeling for packaged food (see § 101.9(c)).

(Comment 101) Several comments supported the proposed nutrients that must be listed in the written nutrition information. Some comments suggested that the written nutrition information also include the weight in grams of the standard menu item. These comments considered that the weight of the standard menu item is an important indicator of portion size and allows consumers to compare similar products more easily, and that including the weight of the standard menu item would be consistent with the Nutrition Facts for packaged foods.

(Response 101) We disagree that we should require that the written nutrition information include the weight in grams for each standard menu item. Section 403(q)(5)(H)(ii)(III) of the FD&C Act specifically requires covered establishments to provide in a written form, available on the premises of the covered establishment and to the consumer upon request, the nutrition information required under clauses (C) and (D) of section 403(q)(1) of the FD&C Act. We are only requiring that covered establishments provide in the written nutrition information the nutrition information specified in section 403(q)(5)(H)(ii)(III) of the FD&C Act, along with *trans* fat, for standard menu items as usually prepared and offered for sale, or in the case of standard menu items that are self-service food or food on display, by displayed food item or per serving. Although the weight of a standard menu item may give some indication of portion sizes, it does not necessarily correlate with how many calories are contained in a food or with what nutrients are in a food. For example, some foods may weigh less than other similar foods but have more calories because of the source of the calories. At this time, we conclude that the written nutrition information required by § 101.11(b)(2)(ii)(A) will allow consumers to make comparisons between menu items and help inform their dietary choices. A covered establishment may voluntarily provide the weight of the standard menu item in the written nutrition information. We also note that for some foods, the weight is already provided as part of the name or description of the standard menu item on the menu or menu board, *e.g.,* a 10-ounce steak versus a 12-ounce steak.

(Comment 102) One comment recommended that the written nutrition information include calcium, potassium, and phosphorus because patients with kidney disease may have diabetes, hypertension, or both. The comment suggested that covered establishments give information on the need to limit these nutrients and to limit sodium.

(Response 102) We disagree with these comments. Section 403(q)(5)(H)(ii)(III) of the FD&C Act requires in relevant part that covered establishments provide, in written form, the nutrition information required under clauses (C) and (D) of section 403(q)(1) of the FD&C Act. Sections 403(q)(1)(C) and (D) of the FD&C Act do not require the disclosure of calcium, potassium, and phosphorus in food labeling. Section 403(q)(5)(H)(vi) of the FD&C Act provides that ''[i]f the Secretary determines that a nutrient, other than a nutrient required under [section 403(q)(5)(H)(ii)(III) of the FD&C Act], should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices, the Secretary may require, by regulation, disclosure of such nutrient in the written form required under [section 403(q)(5)(H)(ii)(III) of the FD&C Act].'' However, the comment did not provide any supporting information showing that the disclosure of calcium, potassium, and phosphorus in the written nutrition information will assist consumers in maintaining healthy dietary practices. At this time, we conclude that the nutrition information specified in section 403(q)(5)(H)(ii)(III) of the FD&C Act, along with *trans* fat information, is sufficient to assist consumers in maintaining healthy dietary practices within the context of section 403(q)(5)(H) of the FD&C Act. If we determine that other nutrient information should be disclosed in the written form required under section 403(q)(5)(H)(ii)(III) of the FD&C Act, we will make changes to such requirements as appropriate. We note that consumers who have a particular disease or health-related condition may be able to use the written nutrition information to follow advice they have received from a health care professional concerning dietary practices relevant to their conditions.

(Comment 103) One comment asked us to permit voluntary declaration of micronutrients such as vitamins and minerals.

(Response 103) We would not object to the voluntary declaration of vitamins and minerals that may be declared on the Nutrition Facts Label of a packaged food (see § 101.9(c)(8)(ii)), provided that the declaration is truthful and not misleading, as required by section 403(a)(1) of the FD&C Act.

(Comment 104) One comment recommended that if future changes are made to the Nutrition Facts of packaged foods, then the requirements for the written nutrition information should be made consistent with such changes.

(Response 104) If future changes are made to the requirements regarding the Nutrition Facts for packaged foods, we will consider whether changes should also be made to the requirements regarding the written nutrition information required by this rule.

(Comment 105) One comment recommended that the nutrient values in the written nutrition information be reviewed and updated yearly or when changes are made.

(Response 105) We agree, in part, and disagree, in part, with this comment. Under § 101.11(c), a covered establishment must have a reasonable basis for its nutrient content declarations. Under section 403(a)(1) of the FD&C Act, covered establishments must also ensure that their nutrient content declarations are truthful and not misleading. To do so, a covered establishment would need to update the written nutrition information when certain changes are made, *e.g.,* as a result of a recipe change that affects the nutrient content of a standard menu item. However, we see no reason why nutrition information for a standard

menu item must be updated on a recurring basis (such as yearly) when there are no changes to the standard menu item or its method of preparation.

(Comment 106) One comment recommended that covered establishments provide references for their nutrient values to consumers on request.

(Response 106) We are not requiring a covered establishment to provide supporting references for the nutrient values in its written nutrition information to consumers upon request. Section 403(q)(5)(H) of the FD&C Act generally requires covered establishments to provide calorie and other nutrition information for standard menu items. Further, as required by section 403(q)(5)(H)(iv) of the FD&C Act, a covered establishment must have a reasonable basis for its nutrient content disclosures. Covered establishments must also ensure that their nutrient content disclosures are truthful and not misleading in accordance with section 403(a)(1) of the FD&C Act. Section 403(q)(5)(H) of the FD&C Act does not require that covered establishments provide supporting references for their nutrient content disclosures to consumers. However, we would not object if a covered establishment provides this information voluntarily.

(Comment 107) Several comments generally agreed that *trans* fat must be included with the written nutrition information. Some comments expressed the view that providing information about *trans* fat is warranted because of concern with partially hydrogenated vegetable oils.

Comments that opposed including *trans* fat in the written nutrition information generally focused on the distinction between ''industrial *trans* fat'' (*i.e., trans* fat chemically manufactured from vegetable oils) and *trans* fat naturally occurring in food such as ruminant animals. Some comments expressed concern that listing such naturally occurring *trans* fat in the written nutrition information, particularly when it is present in small amounts, could lead to problems in States and localities that have banned the use of *trans* fat in restaurants, or could lead consumers to think that a covered establishment is breaking State or local law. These comments stated that eliminating the requirement to list *trans* fat in the written nutrition information, or limiting the listing for *trans* fat to industrial *trans* fat, would prevent such problems. Other comments expressed the view that the health effects of naturally occurring *trans* fat from ruminants may be different from the health effects of *trans* fat chemically manufactured from vegetable oils. Some comments stated that, in Europe, scientists and regulators have not singled out ruminant *trans* fat for pejorative labeling. Some comments stated that naturally occurring *trans* fats derived from high fat ruminant animal products (namely, beef and dairy products) are converted to conjugated linoleic acid, which the comments reported have been associated with health benefits. These comments considered that industrial and naturally occurring *trans* fat should therefore be distinguished on food nutrition labels and menus to give consumers a more accurate assessment of nutritional quality.

(Response 107) We disagree that we should require the declaration of only ''industrial *trans* fat'' in the written nutrition information. For purposes of the current Nutrition Facts label, our regulatory definitions of nutrients (such as for *trans* fat, total fat, or saturated fat) have traditionally been based on chemical definitions. For example, under § 101.9(c)(2)(ii), the declaration of nutrition information on the label and in labeling of a food must contain a statement of the number of grams of *trans* fat in a serving, defined as the sum of all unsaturated fatty acids that contain one or more isolated (*i.e.,* nonconjugated) double bonds in a *trans* configuration. Analytically, this definition captures all *trans* fatty acid isomers that have isolated bonds, regardless of the origin of the *trans* fatty acid. For example, vaccenic acid (one of the most abundant *trans* fatty acids in ruminant fat) is included in the chemical definition of *trans* fat. Therefore, listing the sum of all unsaturated fatty acids that contain one or more isolated double bonds in a *trans* configuration regardless of the source of such *trans* fat is consistent with the requirements for declaring the amount of *trans* fat in a packaged food on the label for such food (see § 101.9(c)(2)(ii)). Further, in the rulemaking to require the declaration of *trans* fat, we responded to comments regarding functional or metabolic aspects of *trans* fatty acids (*e.g.,* their metabolic transformations to other types of fatty acids) rather than on their actual chemical structures, including potential differences between *trans* fat from industrial sources and *trans* fat from ruminant sources. We concluded that we should define *trans* fat based on its chemical definition rather than any functional attributes (68 FR 41434 at 41461, July 11, 2003). The comments provided insufficient information to overturn the conclusion we previously reached about declaring *trans* fat on the label of packaged food.

We also decline to require the declaration of ''industrial *trans* fat'' in the written nutrition information because declaration of ruminant *trans* fat may lead inspectors or consumers to believe that covered establishments are violating State or local requirements in jurisdictions that ban artificial *trans* fat. We recognize that, in the United States, some jurisdictions, such as the State of California (Ref. 34), New York City (Ref. 35), the City of Baltimore (Ref. 36), and Montgomery County, Maryland (Ref. 37) have imposed restrictions on the use of industrial *trans* fat ingredients in food service establishments. However, a *trans* fat declaration of 0.5 grams or more for a standard menu item in the written nutrition information of a covered establishment does not necessarily mean that the covered establishment is violating a State or local requirement that prohibits industrial *trans* fat ingredients. So long as such standard menu item does not contain the restricted *trans* fat ingredients and is otherwise in compliance with the applicable State or local *trans* fat requirement, a *trans* fat declaration of 0.5 grams or more for such standard menu item could mean that the menu item contains a certain amount of naturally occurring *trans* fat. States and localities would be able to continue to enforce requirements restricting artificial *trans* fat ingredients relying on the same measures they already use to determine if establishments under their jurisdiction are using a prohibited ingredient.

We also note that we recently published a tentative determination that partially hydrogenated oils, the source of industrially produced *trans* fat, are not generally recognized as safe for any use in food based on current scientific evidence establishing the health risks associated with the consumption of trans fat (78 FR 67169, November 8, 2013). If this determination is finalized, we will consider whether the *trans* fat requirements of this rule should be amended.

B. Manner of Presentation of the Written Nutrition Information

Proposed § 101.11(b)(2)(ii) would require, in relevant part, that the written nutrition information be presented in a clear and conspicuous manner. We received several comments on this proposed provision. After considering these comments, we have revised the provision to specify that the written nutrition information must be ''clear and conspicuous,'' including in a color, type size, and in a contrasting

background that render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(Comment 108) One comment supported the proposed requirements that the written nutrition information be clear and conspicuous. Some comments asked us to give more guidance on format and on the standard for the written nutrition information to be presented in a clear and conspicuous manner—*e.g.,* that it be easy to read, have a large enough font, have a contrasting background, and not use all capital letters for the names of standard menu items. One comment recommended that we include specifications for font size.

(Response 108) We disagree that we should specify the particular type size and contrasting background that must be used in the written nutrition information, and prohibit the use of all capital letters for the names of standard menu items in the written nutrition information. Section 403(q)(5)(H)(ii) of the FD&C Act requires covered establishments to provide the written nutrition information required by section 403(q)(5)(H)(ii)(III) of the FD&C Act in a clear and conspicuous manner. As discussed later in this document (see the discussion of § 101.11(b)(2)(ii)(D) in section XVI.E), we are providing covered establishments with the flexibility to use different types of media (*e.g.,* flyers, posters, booklets, kiosks) to provide the written nutrition information. Whether the written nutrition information is clear and conspicuous depends on the media through which a covered establishment chooses to provide the written nutrition information. For example, a specific type size and contrasting background may result in written nutrition information that is clear and conspicuous on a tray liner or brochure, but not on a poster that a consumer may view from several feet away. Thus, we are not establishing specific requirements for type size, contrasting background, or use of capital letters for the written nutrition information so that covered establishments have the flexibility to provide the written nutrition information in a clear and conspicuous manner based on the particular media through which the information is presented.

However, we agree that some guidance is needed on the requirement that the written nutrition information be provided in a clear and conspicuous manner. Section 403(f) of the FD&C Act provides that a food will be deemed to be misbranded ''[i]f any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.'' Accordingly, we conclude that in order for the written nutrition information to be clear and conspicuous, the information must be presented in a manner that renders it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Specifically, we have revised § 101.11(b)(2)(ii) to require that the written nutrition information be presented in a clear and conspicuous manner, including using a color, type size, and contrasting background that render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use. We are also revising § 101.11(f) to state that a standard menu item offered for sale in a covered establishment shall be deemed misbranded under sections 201(n), 403(a), 403(f), and/or 403(q) of the FD&C Act if its label or labeling is not in conformity with paragraph (b) or (c) of the section.

(Comment 109) One comment asked us to require that standard menu items in the written nutrition information be listed in the same order as they are on menus and menu boards.

(Response 109) We disagree that we should require covered establishments to list standard menu items in the written nutrition information in the same order as on menus and menu boards. The comment provided no basis for why this particular order of listing standard menu items is the only order that would be useful to consumers. We are providing flexibility for a covered establishment to list its standard menu items in the written nutrition information in a manner that is best suited to its menu offerings, and conclude that the written nutrition information can enable consumers to make informed dietary choices regardless of the order in which the standard menu items are listed.

(Comment 110) One comment responded to our request for comment on whether to require that nutrients that are particularly important for consumers with obesity and diabetes to monitor in order to maintain healthy dietary practices (*e.g.,* total calories, total fat, sodium, sugar) be bolded or placed in a separate table of nutritional content (76 FR 19192 at 19214–19215). This comment opposed such measures because doing so would highlight the negative aspects of food even though the food also has positive nutrients. Another comment supported the bolding of nutrients of concern to consumers with obesity and diabetes, such as saturated fat and sodium.

(Response 110) We disagree that we should decide whether to require measures for highlighting nutrient declarations important to maintain healthy dietary practices for consumers with obesity and diabetes based on a concern that doing so would highlight the ''negative'' aspects of a menu item even though the menu item also has ''positive'' aspects. However, we did not receive sufficient information in the comments to warrant adding a requirement to emphasize certain nutrients, and we are not requiring such a requirement in this rule. The requirements for the written nutrition information in § 101.11(b)(2)(ii) make nutrition information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices.

C. Nutrients in Insignificant Amounts

Proposed § 101.11(b)(2)(ii)(B) would provide that if a standard menu item contains insignificant amounts of all the nutrients required to be disclosed in § 101.11(b)(2)(ii)(A), the establishment is not required to include nutrition information regarding the standard menu item in the written form. Proposed § 101.11(b)(2)(ii)(B) would explain, however, that if the covered establishment makes a nutrient content claim or health claim, the establishment is required to provide nutrition information on the nutrient that is the subject of the claim in accordance with § 101.10. Proposed § 101.11(b)(2)(ii)(B) would provide that covered establishments may present the written nutrition information in a simplified format for standard menu items that contain insignificant amounts of six or more of the required nutrients and proposed § 101.11(b)(2)(ii)(B)(1) would define what is an insignificant amount.

We note that there is an inconsistency regarding the nutrients that must be included in the simplified format between the preamble discussion and the regulatory text in proposed § 101.11(b)(2)(ii)(B)(*2*). In the preamble discussion, we stated: ''In addition, we are proposing that the simplified format must include information on the nutrients required in § 101.9(f)(2)(i) and (ii) (*i.e.,* total calories, total fat, total carbohydrate, protein, and sodium).'' (76 FR 19192 at 19213). However, proposed § 101.11(b)(2)(ii)(B)(*2*)

specified that the simplified format must include information on total carbohydrates, total fat, protein, and sodium, calories from fat, and any other nutrients identified in § 101.11(b)(2)(ii)(A) that are present in more than insignificant amounts. Proposed § 101.11(b)(2)(ii)(B)(*2*) did not specify that the simplified format must include information on total calories, as we intended. In addition, proposed § 101.11(b)(2)(ii)(B)(*2*) did not make it clear that the simplified format must include calories from fat only if calories from fat are present in more than insignificant amounts, as would be consistent with § 101.9(f)(2)(ii). We have revised and redesignating § 101.11(b)(2)(ii)(B)(*2*) so that it contains three separate subparagraphs that more clearly communicate the requirements. As revised, § 101.11(b)(2)(ii)(B)(*2*) requires that the simplified format must include information, in a column, list, or table, on the nutrients specified in § 101.11(b)(2)(ii)(B)(*2*)(*i*) and (*ii*). Section 101.11(b)(2)(ii)(B)(*2*)(*i*) specifies that the simplified format must include information on total calories, total fat, total carbohydrates, protein, and sodium. Section 101.11(b)(2)(ii)(B)(*2*)(*ii*) specifies that the simplified format must include calories from fat and any other nutrients identified in § 101.11(b)(2)(ii)(A) that are present in more than insignificant amounts. Section 101.11(b)(2)(ii)(B)(*3*) specifies that if the simplified format is used, the statement ''Not a significant source of _____'' (with the blank filled in with the names of the nutrients required to be declared in the written nutrient information and calories from fat that are present in insignificant amounts) must be included at the bottom of the list of nutrients.

In the following paragraphs, we discuss comments on proposed § 101.11(b)(2)(ii)(B)(*2*). We are finalizing it without change other than to revise § 101.11(b)(2)(ii)(B)(*2*) to correct the discrepancy between the description of the proposed requirement in the preamble and the regulatory text and to clarify the requirements.

(Comment 111) One comment recommended that the simplified format we proposed in § 101.11(b)(2)(ii)(B)(*2*), when a standard menu item contains insignificant amounts of more than one-half of the nutrients required to be declared in the written nutrition information, include information on fiber. The comment contended that fiber is an important element in considering the overall nutritional value of a certain food, both in addressing obesity and diabetes. The comment stated that only knowing information on the total carbohydrates without information on the fiber will not allow consumers to make sufficiently healthy choices or will undermine their intent to do so.

(Response 111) If a standard menu item has an insignificant amount of six or more of the required nutrients, the simplified format must include information on total calories, total fat, total carbohydrates, protein, and sodium (§ 101.11(b)(2)(ii)(B)(*2*)(*i*)) as well as information on calories from fat and any other nutrient that is present in the food in more than insignificant amounts (§ 101.11(b)(2)(ii)(B)(*2*)(*ii*)). Thus, if fiber is present in a standard menu item at a level that is more than insignificant (*i.e.,* one gram or more), the amount of fiber must appear in the simplified format. On the other hand, if an insignificant amount of fiber is present in a standard menu item, the simplified format must disclose this information through the statement, ''Not a significant source of _____'' (with the blank filled in with ''fiber'' since fiber is required to be declared in the written nutrition information) (§ 101.11(b)(2)(ii)(B)(*3*)). Therefore, the simplified format for the written nutrition information already must include information on fiber, and there is no need to revise proposed § 101.11(b)(2)(ii)(B) to include fiber as recommended by the comment.

D. Variable Menu Items

Proposed § 101.11(b)(2)(ii)(C) would require that, for variable menu items, the nutrition information listed in § 101.11(b)(2)(ii)(A) must be declared as follows for each size offered for sale:

(1) The nutrition information required in § 101.11(b)(2)(ii)(A) must be declared for the basic preparation of the item and, separately, for each topping, flavor, or variable component.

(2) If the calories and other nutrients are the same for different flavors, varieties, and substitutable components of the combination meal, each variety, flavor, and substitutable component of the combination meal is not required to be listed separately. All items that have the same nutrient levels could be listed together with the nutrient levels listed only once.

In the proposed rule, we considered the following options for providing the nutrition information in the written form for a variable menu item:

- Option 1. List the nutrition information for each nutrient in the variable menu item as a range.
- Option 2. List the nutrition information for each component in the variable menu item (the proposed requirement).
- Option 3. If a standard menu item only has two variations (*e.g.* a sandwich with fruit or with fries), provide both numbers for each nutrient in each option with a forward slash between (*e.g.,* 450/700). If three or more options are available, provide the range in calories.

In the proposed rule, we stated that option 2 provides the consumer with all the required nutrient information for each flavor or variety of a variable item, or each component of a combination meal in a format that facilitates quick comparisons between different menu items (76 FR 19192 at 19213). In the following paragraphs, we discuss comments on this proposed provision. We are making no changes in response to these comments.

However, similar to the specific format requirements we established for declaring calories on a menu or menu board for toppings listed on a menu or menu board, where the amount of the topping on the menu item decreases based on the total number of toppings ordered, we are establishing in § 101.11(b)(2)(ii)(C)(*2*) specific format requirements for providing the written nutrition information for toppings if the amount of the topping included on the basic preparation of the menu item decreases based on the total number of toppings ordered for the menu item (such as is sometimes the case with pizza toppings). Section 101.11(b)(2)(ii)(C)(*2*) of the final rule specifies that if the amount of the topping included on the basic preparation of the menu item decreases based on the total number of toppings ordered for the menu item, the nutrients for each topping must be declared as single values representing the nutrients for each topping when added to a one-topping menu item, specifying that the nutrient declaration is for the topping when added to a one-topping menu item. The nutrients for each topping must also be declared for each size of the menu item offered for sale, as required by § 101.11(b)(2)(ii)(C). We are establishing requirements for providing the written nutrition information for variable menu items offered for sale with the option of adding toppings, and specifying the format and manner of such nutrient content disclosures, as required by sections 403(q)(5)(H)(v) and (x)(II)(bb) of the FD&C Act. Section 101.11(b)(2)(ii)(C)(*2*) helps ensure that consumers are given accurate and consistent information about the nutrient of each topping on a menu item. We would not object if a covered establishment voluntarily includes a statement on the written nutrition information explaining how the nutrients per topping might fluctuate if ordering multiple toppings; for example,

such a statement regarding a pizza pie might say, ''Nutrient values per topping may decrease as the number of toppings per pizza increases.'' Section 101.11(b)(2)(ii)(C)(*2*) is therefore consistent with the requirements for declaring calories for toppings listed on the menu or menu board, where the amount of the topping on the menu item decreases based on the total number of toppings ordered.

Because we added this requirement in § 101.11(b)(2)(ii)(C)(*2*) to address the potential variation in nutrient content for each topping based on the total number of toppings ordered, proposed § 101.11(b)(2)(ii)(C)(*2*), which allows items that have the same nutrient values to be listed together with the nutrient values listed only once, is renumbered for the final rule as § 101.11(b)(2)(ii)(C)(*3*). We are replacing the phrase ''substitutable component'' in two places in the first sentence of § 101.11(b)(2)(ii)(C)(*3*) with ''variable component.'' We are making this change for consistency with the term used in § 101.11(b)(2)(ii)(C)(*1*). We also are replacing the phrase ''nutrient levels'' in two places in the final sentence of § 101.11(b)(2)(ii)(C)(*3*) with ''nutrient values.'' We are making this change for consistency with § 101.11(c), which we have revised to consistently use the term ''values'' in the requirements for determination of nutrient content.

(Comment 112) A few comments supported option 2. Some comments opposed the use of slashes for different flavors and considered that slashes would be confusing and unclear because consumers are not used to nutrition information in restaurants.

(Response 112) We are retaining Option 2 in the rule for providing the written nutrition information for variable menu items generally. Option 2 does not specify the use of the slashes opposed by some comments.

E. Form of the Written Nutrition Information

Proposed § 101.11(b)(2)(ii)(D) would permit the written nutrition information required in § 101.11(b)(2)(ii)(A) to be provided on a counter card, sign, poster, handout, booklet, loose leaf binder, or electronic device such as a computer, or in a menu, or in any other form that similarly permits the written declaration of the required nutrient content information for all standard menu items. Proposed § 101.11(b)(2)(ii)(D) would explain that if the written information is not in a form that can be given to the customer upon request, it must be readily available in a manner and location on the premises that allows the customer/consumer to review the written nutrition information upon request.

In the proposed rule, we discussed the flexibility provided by proposed § 101.11(b)(2)(ii)(D) for the written nutrition information and requested comment on whether we should be more prescriptive in the format and manner of providing the written nutrition information in order to ensure they are useful to consumers (76 FR 19192 at 19214). We also stated that we would not object to the use of tray liners or wrappers as a means to provide nutrition information, as long as the tray liners or wrappers are available upon request to the consumers, and the tray liner or wrapper contains nutrition information for all standard menu items offered for sale at the covered establishment (76 FR 19192 at 19214).

In the following paragraphs, we discuss comments on this proposed provision. We are finalizing it without change, except for an editorial change from ''written information'' to ''written nutrition information'' in the final sentence. With this editorial change, § 101.11(b)(2)(ii)(D) will consistently use the same phrase (''written nutrition information'').

(Comment 113) One comment supported our proposal to permit flexibility in how the written nutrition information would be provided but questioned the use of wrappers, arguing that it is unlikely that there would be enough room on a wrapper to list the nutrition information for all standard menu items in a covered establishment and to make the information easily readable. Another comment recommended that § 101.11(b)(2)(ii)(D) specify the media allowed for the written nutrition information, with a petition and approval process for alternate media, rather than include a ''catch-all phrase'' such as ''any other form that similarly permits the written declaration of the required nutrient content information for all standard menu items,'' which was included in proposed § 101.11(b)(2)(ii)(D). Another comment recommended that we expressly recognize that Nutrition Facts labels can be used to convey the written nutrition information.

(Response 113) Section 101.11(b)(2)(ii) specifies that the written nutrition information must be provided in a clear and conspicuous manner, including using a color, type size, and contrasting background that render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use. A covered establishment could use a wrapper if the written nutrition information for all standard menu items offered for sale at the covered establishment can be presented in a clear and conspicuous manner on the wrapper, is available upon request to the consumers, in accordance with § 101.11(b)(2)(ii), and otherwise complies with the applicable sections of the FD&C Act and § 101.11(b)(2)(ii). For example, there may be enough room on a wrapper to include the written nutrition information for all standard menu items in a clear and conspicuous manner when a covered establishment offers for sale a small number of standard menu items.

In addition, § 101.11(b)(2)(ii) ensures that the written nutrition information is presented in a clear and conspicuous manner without prescribing a list of allowed media or the exact format of the written nutrition information. If we amended § 101.11(b)(2)(ii)(D) to specify the particular types of media that can be used by covered establishments to provide the required written nutrition information, as recommended by one comment, § 101.11(b)(2)(ii)(D) would limit the types of media that can be used by covered establishments, including those developed based on technological advancements. Further, § 101.11(b)(2)(ii) would need to amended every time a covered establishment sought to use a type of media not specified. Rather than specify the media allowed for the written nutrition information, we conclude that the public health goal of this rule would be better served by providing flexibility to covered establishments to use any media to provide the written nutrition information in the way that is best suited to their establishments, as long as the written nutrition information is available on the premises of the covered establishment and to the consumer upon request, is clear and conspicuous, and otherwise complies with the requirements of the applicable sections of the FD&C Act and § 101.11(b)(2)(ii). Providing such flexibility satisfies the requirements of section 403(q)(5)(H)(ii)(III) of the FD&C Act while taking into consideration the varying practices at different covered establishments. With this flexibility, the petition and approval process suggested by the comment is unnecessary.

We agree that Nutrition Facts labels can be used to provide the written nutrition information required under § 101.11(b)(2)(ii) for packaged foods, and this rule provides flexibility to do so (see the discussions of § 101.11(b)(2)(iii)(C) in Response 133, and of § 101.11(c)(1) in section XVIII).

(Comment 114) Some comments stated that the written nutrition information should not have to be

provided with carry out menus. The comments recommended that carry out menus could contain a link to the covered establishment's Internet menu where the written nutrition information may be found. Another comment stated that the written nutrition information should be permitted on Internet menus but not required.

(Response 114) We agree with the comments stating that the written nutrition information should not be required with carry out menus. We are not requiring a specific manner for providing the written nutrition information, as long as the written nutrition information is available on the premises of the covered establishment and provided to the consumer upon request, is disclosed in a clear and conspicuous manner, and otherwise complies with the applicable sections of the FD&C Act and § 101.11(b)(2)(ii). If a consumer who orders from a menu such as a carry out menu or an Internet menu requests the written nutrition information, the covered establishment must provide the information to the consumer. For example, if a covered establishment delivers a menu item to a consumer, the covered establishment could deliver the written nutrition information with the menu item if the consumer requests the information. As another example, if a consumer orders from an Internet menu, a covered establishment could provide the written nutrition information on its Web site or include a link directing the consumer to a Web site providing the written nutrition information. Similarly, as suggested by the comments, a covered establishment could provide a link on carry out menus that directs consumers to a Web site providing the written nutrition information. We note that all menus, including carry out menus, and menu boards must include a prominent, clear, and conspicuous statement regarding the availability of the written nutrition information, as required by section 403(q)(5)(H)(ii)(IV) of the FD&C Act.

(Comment 115) Some comments recommended that we require that the written nutrition information be readily available upon request to consumers before ordering. The comments also recommended that the information be provided in a manner that allows consumers to compare the information between different menu items before ordering and without losing their place in line or having to leave the table. The comments stated that if the written nutrition information is not in a form that can be given to the consumer upon request, it must be readily available in a manner and location on the premises that allows the consumer to review the written nutrition information when ordering (*i.e.,* the consumer should be able to see and review both the menu or menu board and the written nutrition information at the same time). One comment recommended that the information be provided at the place where consumers place their orders and not upon request. One comment recommended that we ensure that all consumers have access to the information. The comment maintained that information on a poster or on a computer in a fixed location may not be accessible to the mobility impaired.

(Response 115) We decline to require that covered establishments make the written nutrition information readily available to consumers where consumers place their orders rather than providing such information to consumers upon request. Section 403(q)(5)(H)(ii)(III) of the FD&C Act specifically requires covered establishments to provide the written nutrition information ''to the consumer upon request.'' In addition, nothing in § 101.11(b)(2)(ii) would preclude consumers from requesting the written nutrition information before ordering. We disagree that the rule must require a format and manner of providing the written nutrition information that ensures that a consumer who requests written nutrition information will avoid losing a place in an ordering line or leaving a table. A covered establishment has flexibility to use a format (*e.g.,* a poster) that may be readily seen by consumers even if they do not specifically ask to see it.

We agree that covered establishments must make the written nutrition information available to all consumers, including consumers with mobility impairment, upon request, and must ensure that the information is presented in a clear and conspicuous manner to all consumers. Section 101.11(b)(2)(ii)(D) specifically identifies formats such as on a counter card, sign, poster, handout, booklet, loose leaf binder, or electronic device such as a computer, or in a menu through which a covered establishment may provide the written nutrition information.

XVII. Comments and FDA Response on Proposed § 101.11(b)(2)(iii)—Requirements for Food That Is Self-Service or on Display

A. Applicability of § 101.11(b)(2)(i) to Food That Is Self-Service or on Display

Under sections 403(q)(5)(H)(ii)(I)(aa) and (II)(aa) of the FD&C Act, we proposed to establish requirements for the declaration of calories for standard menu items on menus and menu boards in proposed § 101.11(b)(2)(i). Under section 403(q)(5)(H)(iii), we proposed to establish requirements for the declaration of calories for self-service food and food on display in proposed § 101.11(b)(2)(iii). In the proposed rule, we tentatively concluded that when self-service foods and food on display appear on menus or menu boards, the menus or menu boards must bear the calorie declarations required by sections 403(q)(5)(H)(ii)(I)(aa) and (II)(aa) of the FD&C Act (76 FR 19192 at 19216). In other words, we tentatively concluded that self-service food and food on display that appear on a menu or menu board are subject to both requirements for the declaration of calories—*i.e.,* the requirements in § 101.11(b)(2)(i) applicable to declaration on a menu or menu board and the requirements in § 101.11(b)(2)(iii) applicable to self-service food and food on display.

(Comment 116) One comment disagreed with our tentative conclusion that the proposed requirements for calorie declaration of standard menu items on menus and menu boards (§ 101.11(b)(2)(i)(A)) apply to food on display and self-service food that is also listed on menus and menu boards. The comment asserted that this tentative conclusion is against the plain language of section 403(q)(5)(H) of the FD&C Act and that to require covered establishments to label menu boards and display cases is unnecessary. The comment asserted that only requiring calorie labeling on signs adjacent to food on display and self-service food would provide information at the point of ordering and therefore would be more consistent with the requirement of section 403(q)(5)(H) of the FD&C Act that calorie information be provided on menus and menu boards, as defined in section 403(q)(5)(H)(xi) of the FD&C Act (''the primary writing of the . . . establishment from which a consumer makes an order selection'').

(Response 116) We disagree with this comment. The plain language of section 403(q)(5)(H)(i) of the FD&C Act provides that ''in the case of food that is a standard menu item . . . [the covered] establishment shall disclose the information described in subclauses (ii) *and* (iii)'' (emphasis added). As discussed in the proposed rule, the word ''and'' between the references to subclause (ii) and subclause (iii) indicates that for each standard menu item, including self-service food and food on display, covered establishments must follow the requirements in section 403(q)(5)(H)(ii) of the FD&C Act as applicable and section 403(q)(5)(H)(iii) of the FD&C Act as applicable. Further,

if Congress had meant for section 403(q)(5)(H)(ii) of the FD&C Act not to apply to self-service food and food on display, it could have included an exception for such foods within that section, as it did for foods described in section 403(q)(5)(H)(vii) of the FD&C Act, but it did not include such an exception. See *e.g., Russello* v. *U.S.,* 464 U.S. 16, 23 (1983) (''[W]here Congress includes particular language in one section of a statute but omits it in another section of the same [statute], it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'') (internal citations omitted). In addition, a consumer may make his or her order selection by using information provided on a traditional menu or menu board or on a sign adjacent to a self-service food or food on display. Disclosing calorie information for self-service food and food on display on traditional menus and menu boards, where such menus and menu boards list self-service food and food on display, and on signs adjacent to self-service food and food on display would help ensure that consumers are able to see the calorie declarations before making order selections and is consistent with the plain language of sections 403(q)(5)(H)(ii) and (iii) of the FD&C Act.

Therefore, when a self-service food or food on display is listed on a menu or menu board, the food is subject to both § 101.11(b)(2)(i) for declaration of calories on menus and menu boards and to § 101.11(b)(2)(iii) for foods on display.

B. Placement of Calories for Self-Service Foods and Foods on Display

Proposed § 101.11(b)(2)(iii)(A) would require that when a self-service food or food on display is already accompanied by an individual sign, adjacent to the food, that provides the food's name, price, or both, the calories per item or per serving must be provided on the sign. When a self-service food or food on display is not already accompanied by an individual sign, adjacent to the food, that provides the food's name, price, or both, the covered establishment must place a sign adjacent to each food with the number of calories per serving or per item in a clear and conspicuous manner.

In the following paragraphs, we discuss comments on this proposed provision. After considering these comments, we have revised the provision to provide more options for the declaration of calories for self-service food and food on display and to require that if the individual sign does not already include the serving, the amount of the serving on which the calories are based must also be provided on the sign, *e.g.,* ''150 calories per scoop.''

We also are correcting the introductory text in § 101.11(b)(2)(iii) by inserting a hyphen between ''self'' and ''service.''

(Comment 117) Several comments supported the requirements in proposed § 101.11(b)(2)(iii). Some comments recommended that foods on display be labeled with calorie information regardless of whether the food is served by the customer or employee. Some comments asked us to clarify that a calorie declaration is also required for displayed foods such as pastries and doughnuts at bakeries and ice cream behind a glass case in an ice cream shop.

(Response 117) The definition of ''self-service food'' includes restaurant-type food that is served by the customers themselves, and the definition of ''foods on display'' includes restaurant-type food that is visible to the customer before the customer makes a selection. In general, pastries, donuts, and ice cream on display, such as behind a glass case, meet the definition of food on display. Under these definitions, the requirements in proposed § 101.11(b)(2)(iii) apply to standard menu items that are foods served by the customers themselves as well as to standard menu items that are foods such as pastries, donuts, and ice cream that are behind a glass case or in an ice cream shop and are served by an employee.

(Comment 118) Some comments requested flexibility to determine the placement of calorie information that works best for them. Some comments recommended that the calorie declaration be permitted to be placed on a single sign, or electronically via kiosks or touch screen computers, and not on all individual signs. One comment asserted that, for buffets, the layout and number of items make it difficult to display signs for hundreds of items without cluttering the space or obstructing the view. The comment also asserted that customers may inadvertently move the signs, and therefore, the calorie declaration should instead appear on counters or in display cases.

Some comments stated that buffets are unique because foods vary and change often. For example, according to one comment, a restaurant may have as many as 175 different menu items in a meal period. One comment stated that the foods are changed multiple times a day, the items may change from day to day, and the rotation of foods would create confusion if the food signs are not accurately changed with each new menu item.

One comment stated that the location and size of the food signs are affected by health and safety regulations because the food signs could lead to contamination of the food and because food signs adjacent to heated areas or grills for food items cooked to order could create a hazard. Moreover, the comment noted that multiple menu items may be simultaneously prepared to order on open grills. This comment recommended that these types of restaurants be permitted to place the calorie information on individual signs adjacent to or in close proximity to the food by using a variety of options (*e.g.,* sneeze guards; partition or placard; menu board or placard adjacent to the buffet with all the items listed with nutrition content; pamphlet adjacent to the buffet; written or electronically displayed information using kiosks; tablet computers; or touch screen computers).

(Response 118) We agree that placing individual signs adjacent to a self-service food or food on display may pose a hazard in certain circumstances, such as when there is an open heat source (such as a grill) in close proximity to the sign that could create a fire hazard. We also agree that more flexibility is needed for foods that are constantly being replenished or changed. Therefore, to provide more flexibility and reduce the potential for a sign used to declare calories for self-service food or food on display to create a hazard, we have revised § 101.11(b)(2)(iii)(A) to allow covered establishments to declare calories for standard menu items that are self-service or on display, and the serving or unit used to determine the calorie content (*e.g.,* ''per scoop'' or ''per muffin''), using one of the following options:

- On a sign, adjacent to and clearly associated with the corresponding food item;
- On a sign attached to a sneeze guard with the calorie declaration and the serving or unit used to determine the calorie content above each specific menu item so that the consumer can clearly associate the calorie declaration with the standard menu item. For example, if a buffet has several menu items in the serving display case including, in particular, a broccoli and cheese casserole, the sign attached to the sneeze guard right above the broccoli and cheese casserole may declare the calories, *e.g.,* ''200 calories

per scoop.'' If it is not clear to which food the calorie declaration and serving or unit refers, then the sign must also include the name of the food, *e.g.,* ''Broccoli and cheese casserole—200 calories per scoop;'' or

• On a single sign or placard listing the calorie declaration for several menu items along with the names of the menu items, so long as the sign or placard is located where a consumer can view the name, calorie declaration, and serving or unit of a particular menu item while the consumer is selecting that item. The sign must list the names of the menu items along with their corresponding calorie declarations. For example, for a soup station, the sign or placard must list all the soups that are available at that station along with each calorie declaration, *e.g.,* ''chicken noodle soup, 125 calories per cup,'' ''minestrone soup, 100 calories per cup.'' This sign may be placed on the wall behind the station, on a sign at the beginning or end of the station, or at another location so long as the consumer can read the name, calorie declaration, and serving or unit of a particular menu item while selecting the menu item.

Each option, when implemented appropriately, associates the calorie declaration with the appropriate food on display or self-service food to help ensure that consumers can see such declarations when making their selections.

(Comment 119) In the proposed rule, we stated that placing a separate sign with calorie information adjacent to a food that is already accompanied by a sign bearing its name, price, or both, could make it more difficult for consumers to clearly associate the calorie information with its corresponding self-service food or food on display (76 FR 19192 at 19215). We requested comment on whether establishments that already provide an individual sign identifying each food on display or self-service food with its name, price, or both should have the option of providing a separate individual sign for each food on display or self-service food for the calorie declaration, so long as the sign with the calorie declaration is adjacent to and clearly associated with its corresponding food.

One comment recommended that calories appear on the same sign as the name or price of the food rather than on a separate sign, because more than one sign could cause confusion.

(Response 119) We acknowledge the comment's concern, which mirrored a concern we raised in the proposed rule. However, in light of the recommendations in the comments describing the need for more flexibility in declaring calories for self-service foods and foods on display, we have concluded that there are a number of ways in which a covered establishment can comply with section 403(q)(5)(H)(iii) of the FD&C Act to provide calorie declarations for self-service foods and foods on display based on the establishment's particular operations, including the use of a separate sign placed adjacent to a self-service food or food on display that is clearly associated with the food (see Comment 118 and Response 118). Therefore, we have revised § 101.11(b)(2)(iii)(A) by removing the sentence requiring that when a self-service food or food on display is already accompanied by an individual sign, adjacent to the food, that provides the food's name, price, or both, the calories per item or per serving must be provided on the sign. In addition, we have revised § 101.11(b)(2)(iii)(A) by providing options for a covered establishment to provide calorie declarations on signs for self-service food and food on display, including the options described in Response 118. We are making these changes based on the reasons discussed in Response 118 and because we recognize that existing individual signs for these foods may be quite small and either not have enough space for the calorie declaration, or cause the sign to be so crowded that the calorie declaration may not be easily read or clear and conspicuous enough for the consumer to read the information. (See, *e.g.,* the discussions in Comment 126 and Response 126, and in Comment 127 and Response 127, about the requirements for type size of the calorie declaration when a self-service food or food on display is already accompanied by a sign with the food's name, price, or both.)

C. Declaring Calories ''Per Item'' or ''Per Serving''

Proposed § 101.11(b)(2)(iii)(A)(*1*) would specify that for purposes of § 101.11(b)(2)(iii)(A), ''per item'' means per each discrete unit offered for sale, for example, a bagel, a slice of pizza, a muffin, or a multi-serving food such as a whole cake. Proposed § 101.11(b)(2)(iii)(A)(*2*) would specify that for purposes of § 101.10(b)(2)(iii)(A), ''per serving'' means: (1) Per each common household measure, *e.g.,* cup, scoop, tablespoon, offered for sale as dispensed using a serving instrument such as a scoop, ladle, cup, or measuring spoon; or (2) per unit of weight offered for sale, *e.g.,* per half pound or pound.

In the following paragraphs, we discuss comments on these proposed provisions. After considering these comments, we are:

• Deleting ''a multi-serving food such as a whole cake'' from the list of examples of what the rule means by ''per item.'' As discussed in section VI.C, the definition of ''restaurant-type food'' established in the rule includes food that is usually eaten on the premises, while walking away, or soon after arriving at another location, and whole cakes that are self-service food or food on display are not likely to meet this definition.

• Providing the options to declare calories ''per serving instrument'' or ''per common household measure'' in separate subparagraphs, rather than in the same subparagraph, to emphasize that these are distinct alternatives for declaration of calories ''per serving.''

• Revising the examples of what we mean by ''per unit of weight offered for sale'' to be ''per quarter pound'' or ''per 4 ounces.'' We are making this change because examples of a quarter pound or 4 ounces are more likely to reflect a serving of self-service food or food on display.

• Changing § 101.11(b)(2)(iii)(A)(*1*) and (b)(2)(iii)(A)(*2*) to read ''paragraph (b)(2)(iii)(A) of this section'' rather than ''§ 101.11(b)(2)(iii)(A)'' to be more consistent with FDA's general practice. We note that the proposed rule had identified the cross-reference as ''§ 101.10(b)(2)(ii)(A).'' We revised this to ''§ 101.11(b)(2)(iii)(A)'' in the correction document, but did not identify the format change at that time.

(Comment 120) One comment suggested that the portion of the standard menu item used to calculate the calorie content also be clearly displayed in the same font, color, and size as the item name and be posted on or next to the available food on display or self-service food.

(Response 120) We agree that the serving or unit of a standard menu item that is a self-service food or food on display used to determine the calorie content for such food must be included in the calorie declaration. Without information about the serving or unit of a self-service food or food on display, the consumer would not be able to ascertain the calorie content of the amount of food that would be consumed. This would defeat the purpose of the calorie declaration. Therefore, we have revised § 101.11(b)(2)(iii)(A) to require that the calorie declaration for foods on display and self-service food include the serving or unit on which the calorie content is based. The requirements in

§ 101.11(b)(2)(iii)(A)(*3*)(*ii*) for font size and color will apply to the entire calorie declaration, including the serving or unit used to determine calorie content. (See the discussion of § 101.11(b)(2)(iii)(A)(*3*)(*ii*) in section XVII.E.2.)

(Comment 121) One comment asked us to allow a covered establishment to list nutrition information for standard menu items that are self-service or on display per serving size and requested clarification on how the RACC would be used in this case. The comment asked us to keep in mind that many retailers would like to align their calorie declarations for menu items with serving sizes for packaged food so as not to have two different serving sizes.

(Response 121) In Response 65 in section XI, we explained why a calorie declaration for a multiple-serving standard menu item that is not self-service or on display must declare ''the number of calories contained in the standard menu item, as usually prepared and offered for sale'' instead of per RACC (to the extent that there is a RACC for such standard menu item). Similarly, we disagree that a calorie declaration for a standard menu item that is a self-service food or food on display should be declared per RACC or per serving size used on packaged food, unless such RACC or serving size is the portion or serving used by the covered establishment to display or otherwise offer such standard menu item for sale. Self-service food and food on display may be portioned differently than a RACC or serving size used on packaged food. Section 403(q)(5)(H) of the FD&C Act does not require a covered establishment to prepare and offer standard menu items in particular sizes or amounts, such as RACCs or serving sizes used on packaged foods. Instead, section 403(q)(5)(H)(iii) of the FD&C Act expressly requires covered establishments to disclose the number of calories for self-service foods and foods on display ''per displayed food item or per serving.'' Accordingly, a covered establishment may choose the portion or serving of the food that it offers for sale, and must base the calorie declaration for a self-service food or food on display per displayed item (*e.g.,* ''per muffin'') or per serving (*e.g.,* ''per scoop'') as offered for sale.

(Comment 122) A few comments expressed concern with portion sizes and with declaring nutrient values for items that vary in size and content (*e.g.,* baked potato, chicken breast). Some comments asked for guidance on serving sizes for calorie declarations pertaining to foods on display. One comment asked us to clarify that the calories should be declared per item or serving as offered for sale and not for a portion of a food item that is smaller than the food offered for sale. For example, a covered establishment that offers a large muffin for sale should be required to declare calories per item (*i.e.,* the large muffin) and should not be permitted to declare calories per serving and describe the large muffin as containing two servings.

One comment maintained that calories of foods at salad bars should be declared per cup and not per serving. Several comments asked us to require that calories be based on serving utensil sizes where possible. One comment recommended that we require the same serving size as for packaged food if no utensil is used. The comment suggested that calories be declared per cup if tongs are used for lettuce at a salad bar. The comment suggested that the rule be revised to include:

(iii) The following must be provided for food that is self-service or on display.

''(1) Calories must be provided for each standard serving size offered, *e.g.,* each beverage cup size offered for a fountain beverage dispenser or each container size available for a deli salad.

(2) For purposes of § 101.10(b)(2)(iii)(A), ''per item''' means per each discrete unit offered for sale—for example, a bagel, a muffin, a sandwich, or a multi-serving food, such as a whole cake.

(3) If the item is not sold as a discrete unit, it can be labeled per serving. For purposes of § 101.10(b)(2)(iii)(A), ''per serving''' means:

(i) Per each scoop or container as dished up using the serving instrument provided, such as a ladle, cup, or measuring spoon, or per weight or container-size offered, such as a quarter pound of potato salad or a container of soup.

(ii) If the item is not served using a ladle or other measuring instrument or per container size, the item must be labeled in the common household measure closest to the Reference Amount Customarily Consumed (RACC) for that item, *e.g.,* per cup or tablespoon.''

(Response 122) We agree that a calorie declaration for a self-service food or food on display per displayed food item should be declared for the entire item as offered for sale and not based on a portion of the food item that is smaller than the food item offered for sale. For example, if a covered establishment offered a muffin for sale as a self-service food or food on display, the establishment should declare calories for the entire muffin rather than just a portion of the muffin (*e.g.,* one-half or one-third of the muffin) because the entire muffin is the standard menu item offered for sale by the establishment.

We also agree with the comment asserting that the rule should be revised to require that when a self-service food or food on display is offered for sale per displayed food item, meaning per a discrete unit offered for sale, such as a bagel, a slice of pizza, or a muffin, the calorie declaration for such food should be based on the discrete unit offered for sale rather than another amount. In the proposed rule, we tentatively concluded that for self-service food or food on display that is displayed per item, where the item represents one serving, the calorie declaration should be per item (76 FR 19215). We affirm this conclusion.

We also agree with the comment asserting that the rule should be revised to require that when a self-service food or food on display is not offered for sale per displayed food item, the calorie declaration for such food should be based on the serving offered for sale. In the proposed rule, we tentatively concluded that for self-service food or food on display that is not displayed per item (*e.g.,* potato salad at a buffet or ice cream at an ice cream parlor), the calorie declaration should be per serving (76 FR 19215). We affirm this conclusion.

For these reasons, we have revised § 101.11(b)(2)(iii)(A) to further specify that a covered establishment must declare calories for a self-service food or food on display per displayed food item, or if the food is not sold in a discrete unit, per serving as offered for sale. Under § 101.11(b)(2)(iii)(A)(*1*), ''per displayed food item'' means per each discrete unit offered for sale, for example, a bagel, a slice of pizza, or a muffin. Accordingly, if a covered establishment offers a food that is self-service or on display for sale in a discrete unit, such as a muffin, the establishment would have to declare calories for the food per such discrete unit offered for sale, and not based on a different amount.

As discussed in Response 65 and Response 121, we disagree that the rule should require that calories for self-service food and food on display be declared per RACC and, therefore, we are not revising § 101.11(b)(2)(iii)(A)(*2*) to require that an item that is not served using a measuring instrument be labeled in the common household measure closest to the RACC for that item. However, we agree that specifying that calories for a self-service food or food on display be disclosed per displayed food item, if applicable, and providing other options to declare calories ''per serving

instrument'' and ''per common household measure'' in separate subparagraphs, as suggested by this same commenter, would provide a clearer framework regarding how calorie declarations must be provided for self-service foods and foods on display. Therefore, in addition to the revisions we made to § 101.11(b)(2)(iii)(A)(*1*) as described previously, we have revised § 101.11(b)(2)(iii)(A)(*2*)(*i*) to specify that, for the purposes of § 101.11(b)(2)(iii)(A), ''per serving'' means (1) per serving instrument used to dispense the food offered for sale, provided that the serving instrument dispenses a uniform amount of the food (*e.g.,* a scoop or ladle); or (2) if a serving instrument that dispenses a uniform amount of food is not used to dispense the food, per each common household measure (*e.g.,* cup or tablespoon) offered for sale or per unit of weight offered for sale (*e.g.,* per quarter pound or per 4 ounces). As revised, §§ 101.11(b)(2)(iii)(A)(*1*), and (b)(2)(iii)(A)(*2*)(*i*) to (b)(2)(iii)(A)(*2*)(*ii*) establish a logical hierarchy for determining how to declare calories for a self-service food or food on display. For example, if a covered establishment offered a self-service food for sale in a discrete unit, such as a muffin, the establishment would have to declare calories for the muffin as a whole. If the covered establishment offered another self-service food for sale, but the food was not offered for sale in a discrete unit, such as pasta salad, the establishment would have to declare calories for the food ''per serving'' as defined in § 101.11(b)(2)(iii)(A)(*2*). Under § 101.11(b)(2)(iii)(A)(*2*)(*i*), the covered establishment would have to declare calories for the pasta salad per serving instrument used to dispense the pasta salad if the serving instrument dispensed a uniform amount of the food (*e.g.,* per scoop or ladle). If the covered establishment used a serving instrument that does not dispense a uniform amount of the food, such as tongs, declaring calories per that serving instrument used to dispense the food would not be appropriate because the calorie declarations would not always be consistent with the amount of food dispensed, and therefore the covered establishment would look to the remaining options to declare calories, which include declaring calories per common household measure or per unit of weight offered for sale (in § 101.11(b)(2)(iii)(A)(*2*)(*ii*)). If a covered establishment offers food for sale per unit of weight, and the unit of weight offered for sale is in ounces, then it would be required to declare calories per ounce (or per some number of ounces)—*i.e.,* using the same unit of weight (ounces) as the unit of weight offered for sale.

We disagree that we should establish specific examples of portion sizes in the rule or add details such as specifying that a ''container of soup'' is an appropriate portion size for soup. A covered establishment has flexibility to establish the portion sizes for standard menu items offered for sale in such establishment.

As discussed in section VI.C, the definition of ''restaurant-type food'' generally covers food that usually is eaten on the premises, while walking away, or soon after arriving at another location. Foods (such as whole cakes and deli salads that are sold from a display case rather than from a salad bar) that are grocery-type items that consumers usually store for use at a later time or customarily further prepare would not be included within the meaning of ''restaurant-type food.'' Thus, we have deleted ''a multi-serving food such as a whole cake'' from § 101.11(b)(2)(iii)(A)(*1*). We decline to add ''deli salad'' as an example in what we mean by ''per serving'' because doing so could incorrectly imply that a deli salad sold at a deli counter as a grocery-type item is likely to be covered by the rule. We are adding § 101.11(b)(2)(iii)(A)(*2*)(iii) to specify what we mean by ''per serving'' for self-service beverages—*i.e.,* per total number of fluid ounces in the cup in which a self-service beverage is served and, if applicable, the description of the cup size (*e.g.,* ''140 calories per 12 fluid ounces (small)''). See Response 125 in the next section of this document for an explanation of this new provision.

(Comment 123) One comment noted that some foods on display are offered in different flavors or varieties such as ice cream or doughnuts. The comment asked us to clarify that a covered establishment may disclose the nutrition information for such items by using a range per serving (or one of the other options being considered for other variable menu items).

(Response 123) A standard menu item on display may meet the definition for a variable menu item in § 101.11(a) when it is offered for sale in different flavors, varieties, or combinations, and is listed on a menu or menu board as a single menu item. When this is the case, the format requirements for variable menu items in § 101.11(b)(2)(i)(A)(*4*) through (b)(2)(i)(A)(*8*) would apply to calories declared on the menu or menu board. Accordingly, to the extent that standard menu items on display offered for sale in different flavors or varieties are listed as single menu items on menus or menu boards, a covered establishment would be required to declare calories on such menus and menu boards for such foods using the same methods applicable to other variable menu items, including ranges, as specified in § 101.11(b)(2)(i)(A)(*4*) through (b)(2)(i)(A)(*8*). However, when these foods are on display, they would also be subject to the requirements of section 403(q)(5)(H)(iii) of the FD&C Act and § 101.11(b)(2)(iii). For a standard menu item that is a self-service food or food on display, section 403(q)(5)(H)(iii) of the FD&C Act requires the covered establishment to ''place adjacent to each food offered a sign that lists the calories *per displayed food item or per serving''* (emphasis added). Typically, a standard menu item that is on display is presented to the consumer as a unique menu item, in that the food is made visible to the consumer, and the consumer can see what other standard menu items are available, including other standard menu items that come in different flavors, varieties, or combinations, such as various muffins or pastries in a display case. Because these standard menu items typically are on display in a manner that allows consumers to see each menu item individually, as well as the other menu items available, including menu items offered in different flavors or varieties, the way in which these items are offered for sale is not analogous to standard menu items that come in different flavors or varieties but are listed as a single menu item on a menu or menu board. For example, a covered establishment may offer for sale different flavors of ice cream (*e.g.,* vanilla, chocolate, strawberry) in individual containers in a display case visible to consumers. In this situation, because the consumer can see each flavor of ice cream offered for sale, the consumer should also be able to see the number of calories contained for each flavor of ice cream offered for sale. As a result, the covered establishment would be required to place a sign adjacent to each flavor of ice cream in the display case that lists the calories per each individual displayed food item or per serving in accordance with § 101.11(b)(iii).

D. Declaring Calories ''Per Serving'' for Self-Service Beverages

In the proposed rule, we discussed the serving size of beverages following our discussion of the declaration of calories for self-service food and food on display ''per item'' and ''per serving'' (76 FR 19192 at 19216). We recognized that covered establishments may have different sizes for beverages that are

listed on the menu as small, medium, and large and stated that we were considering whether the amount of calories declared should be based on the number of ounces. In the proposed rule, we anticipated that if we adopt this view in the final rule, we would not object to the covered establishment listing the number of ounces as part of the size declaration, *e.g.,* ''140 calories per 12 ounces (small).'' We requested and received comment on this issue. After considering these comments, we are establishing a new provision to specify that, for beverages that are self-service or on display, ''per serving'' means per total number of fluid ounces in the cup in which a self-service beverage is served and, if applicable, the description of the cup size (*e.g.,* ''140 calories per 12 fluid ounces (small)'') (§ 101.11(b)(2)(iii)(A)(*2*)(*iv*)). As an operational companion to new § 101.11(b)(2)(iii)(A)(*2*)(*iii*), we also are establishing a new provision (§ 101.11(b)(2)(iii)(A)(*3*)(*iii*)) to require that calorie declarations for self-service beverages be accompanied by the term ''fluid ounces'' and, if applicable, the description of the cup size (*e.g.,* ''small,'' ''medium''). (See also Response 129 in section XVII.E.3 of this document.)

(Comment 124) One comment noted that the proposed rule did not address the issue of ice fill for the declaration of calories for beverages. The comment asked us to permit covered establishments to calculate calories based on their standard ice fill as long as the level of ice fill is disclosed to consumers. The comment recommended that we expressly permit, regardless of whether there is a standard ice fill, the following statement regarding ice fill: ''Calorie content may vary based on the amount of ice used.''

(Response 124) We previously addressed this comment with respect to beverages that are not self-service (see the discussion of § 101.11(b)(2)(i)(A)(*9*) in section XIII). Under section 403(q)(5)(H)(iii) of the FD&C Act, calories for standard menu items that are self-service foods and foods on display, including ''soft drinks,'' must be declared ''*per displayed food item or per serving''* (emphasis added). For beverages that are self-service, the actual amount of a beverage dispensed by consumers will vary depending on the size of the cup and the amount of ice or beverage that a consumer may add to the cup. For these reasons, the provisions we are establishing in this rule for self-service beverages require declaration of calories based on the full volume of the cup (*i.e.,* without ice), and do not provide for the declaration of calories based on a standard beverage fill or standard ice fill. (See discussion of § 101.11(b)(2)(iii)(A)(*2*)(*iii*) of the final rule immediately following.)

We would not object to a covered establishment posting a statement (at the self-service beverage dispenser, on the menu or menu board, or both) indicating that the calories for the self-service beverages may vary depending on the amount of ice dispensed (*e.g.,* ''calorie content may vary based on the amount of ice used'').

(Comment 125) One comment asserted that calories for self-service beverages should not be listed for an ''appropriate serving size'' such as 12 ounces because this may not correspond to the sizes that are actually sold in the covered establishment.

(Response 125) We agree that the number of ounces in a beverage cup may vary between covered establishments and we agree that the rule should not establish ''an appropriate serving size'' for self-service beverages. We also agree that consumers should be given calorie information based on the number of ounces in the cup which the consumer uses to dispense a self-service beverage. Section 403(q)(5)(H)(iii) of the FD&C Act provides that calories for self-service foods and foods on display be declared ''*per displayed food item or per serving''* (emphasis added). For self-service beverages, the serving units depend, in part, on the cups provided by the covered establishment to consumers for use at the self-service beverage dispenser. The actual amount of beverage dispensed by consumers will vary based on the size of the cup and the amount of beverage that a consumer dispenses into the cup. As already discussed in Response 124, the actual amount of beverage dispensed by consumers also will vary based on the amount of ice that a consumer may add to the cup, and in contrast to some non-self-service beverages offered for sale by a covered establishment, self-service beverage dispensers typically do not have a standard beverage fill or standard ice fill. In addition, for any given establishment, the cups provided for self-service beverages may be in a single size or may be in different sizes, *e.g.,* in cups labeled ''small,'' ''medium,'' or ''large.'' Further, as already noted, covered establishments may have different sizes for beverages that are listed on menus as small, medium, and large. For these reasons, we are specifying that, for self-service beverages, calories ''per serving'' within the meaning of section 403(q)(5)(H)(iii) of the FD&C Act must be based on the number of ounces in the cup in which the beverage is served.

Therefore, § 101.11(b)(2)(iii)(A)(*2*)(*iii*) of the final rule specifies that, for purposes of § 101.11(b)(2)(iii)(A), ''per serving'' means, for beverages that are self-service, per total number of fluid ounces in the cup in which a self-service beverage is served and, if applicable, the description of the cup size (*e.g.,* ''140 calories per 12 fluid ounces (small)''). As an operational companion to § 101.11(b)(2)(iii)(A)(*2*)(*iii*), we also are establishing specific format requirements applicable to the declaration of calories for self-service beverages.

Section 101.11(b)(2)(iii)(A)(*3*)(*iii*) of the final rule requires that, for self-service beverages, calorie declarations must be accompanied by the term ''fluid ounces'' and, if applicable, the description of the cup size (*e.g.,* ''small,'' ''medium''). By providing the number of fluid ounces in the cup in which the self-service beverage is served and a description of the size of the cup, if applicable, along with the calories for the self-service beverage, the calorie declaration will provide necessary context regarding the amount of the beverage (*i.e.,* the number of fluid ounces dispensed) upon which to base the number of calories for the self-service beverage. This information will enable consumers to determine how many calories are contained in a serving of the self-service beverage in a direct and consistent manner.

E. Manner of Declaring Calories for Self-Service Foods and Foods on Display

1. Increments of Calories

Proposed § 101.11(b)(2)(iii)(A)(*3*)(*i*) would require that calories for self-service food and food on display be declared to the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increments above 50 calories except that amounts less than 5 calories may be expressed as zero.

We received no comments on this proposed provision and are finalizing it without change, except for an editorial change to express ''nearest 10-calorie increments'' in the singular (*i.e.,* ''nearest 10-calorie increment'').

2. Requirements for Declaration of Calories To Be Clear and Conspicuous

Proposed § 101.11(b)(2)(iii)(A)(*3*)(*ii*) would require that if the food is not already accompanied by a sign with the food's name, price, or both, the calorie declaration, accompanied by the term ''Calories'' or ''Cal'', must appear on a

sign adjacent to the standard menu item in a clear and conspicuous manner if the food is not already accompanied by a sign with the food's name, price or both. If the food is already accompanied by a sign with the food's name, price, or both, the calorie declaration and the term ''Calories'' or ''Cal'' must appear on that sign in a type size no smaller than the name or price of the menu item whichever is smaller, in the same color or a color that is at least as conspicuous as that name or price using the same contrasting background. Proposed § 101.11(b)(2)(iii)(A)(*3*)(*ii*) inadvertently included the clause ''if the food is not already accompanied by a sign with the food's name, price, or both'' in two locations within the provision.

In the proposed rule, we requested comment on whether additional or more specific formatting requirements are necessary (76 FR 19192 at 19215). In the following paragraphs, we discuss comments on the proposed provision. We also discuss comments in response to our specific request on whether additional or more specific formatting requirements are necessary. After considering these comments, we are finalizing it with the following changes:

- For consistency with the provisions we are establishing in § 101.11(b)(2)(iii)(A), we are specifying that the calorie declarations must include the amount of the serving on which the calories are based.
- For consistency with the provisions we are establishing in § 101.11(b)(2)(iii), we are making a series of changes to address options that a covered establishment can use to declare calories for self-service food or food on display, including the use of an additional sign even if a food is already accompanied by a sign with the food's name, price, or both.
- To provide for a consistent approach to the requirements for a contrasting background throughout the rule, we are providing additional flexibility for the contrasting background used for the calorie declaration and making a conforming editorial change to the grammatical construction of the requirement for the color used for the calorie declaration.
- As an editorial correction for clarity, we are inserting ''the type size of'' between ''no smaller than'' and ''the name or price.''

(Comment 126) One comment recommended that we require the calorie declaration to be clear and conspicuous but not in a type size as large as the food's name or price. The comment maintained that if these foods already have signs, there is likely no room for calorie declarations.

One comment pointed out that fountain machines have small signs or ''valve decals'' on which the name is placed. According to the comment these valve decals can be as small as 0.7 x 1 inches to 5.25 x 5.25 inches and these signs do not have enough space to list the calorie declarations. The comment recommended that a covered establishment not have to list the calories adjacent to the dispenser if calories for fountain drinks are listed on menus and menu boards and the written nutrition information is available, because to do so would be burdensome.

One comment asked us to allow a covered establishment to use a sign or placard placed adjacent to the fountain beverage machine that lists the calories. Another comment recommended that calorie declarations for self-serve beverages be posted on menus, menu boards, or brochures, and not at the dispensers. One comment recommended that calorie declarations be listed both on the menu boards and the dispenser for each type of beverage dispensed.

One comment noted that brand names are stylized and therefore the names of beverages may be in different type sizes. The comment maintained that tying the type size of the calories to the name of the beverage would result in differing sizes for calories, which could be confusing.

(Response 126) Section 403(q)(5)(H)(iii) of the FD&C Act requires covered establishments to place adjacent to each standard menu item that is a self-service food or food on display, including self-service beverages, a sign that lists calories per displayed food item or per serving. As discussed previously in this document (see Response 116), a covered establishment must also declare calories on a menu or menu board, and follow all applicable requirements of § 101.11(b)(2)(i) for declaration of calories on the menu or menu board, when self-service food or food on display is listed on the menu or menu board.

We acknowledge that there may be space limitations on signs used for self-service food (including valves used for self-service beverages) and foods on display. As already discussed in section XVII.B, we have revised § 101.11(b)(2)(iii)(A) to provide more options for the declaration of calories for self-service food and food on display, including the use of additional signs, signs attached to a sneeze guard, or a single sign or placard listing the calorie information for several standard menu items that are self-service or on display provided that certain conditions are met. These options provide additional flexibility for a covered establishment that offers self-service foods, including self-service beverages, to declare the calories in a manner that works best for it. For example, a covered establishment has an option to declare the calories on a sign separate from the sign containing the food's name and price, provided the calories are clearly associated with the particular food item. Doing so would no longer link the type size requirements for a self-service beverage to those for the name of the beverage. As a result, we have revised § 101.11(b)(2)(iii)(A)(*3*)(*ii*) to provide that if a calorie declaration for a self-service food or food on display is provided on a sign that includes the food's name, price, or both, the calorie declaration, accompanied by the term ''Calories'' or ''Cal'' and the amount of the serving or displayed food item on which the calorie declaration is based, must be in a type size no smaller than the type size of the name or price of the food, whichever is smaller, in the same color, or a color that is at least as conspicuous as that used for the name or price, using the same contrasting background, or a background at least as contrasting.

(Comment 127) One comment addressed the different proposed requirement for self-service food and food on display depending on whether the food is already accompanied by a sign with the food's name, price, or both. If the food is already accompanied by such a sign, the comment said that the proposed provision would be prescriptive with respect to type size, color, and contrast requirements for the calorie declarations, whereas if the food is not already accompanied by such a sign, the proposed provision would be less prescriptive by merely requiring that calorie declarations be ''clear and conspicuous.'' The comment asked us to revise the rule to establish the less prescriptive requirement that the calorie information be clear and conspicuous regardless of whether the food is accompanied by a sign with the name or price of the food. The comment considered that a prescriptive requirement linked to type size, color, and contrast requirements of the food's name, price, or both would be misleading because it would imply that the number of calories in a food, which is just one attribute of the food, is as important as the name of a food.

One comment stated that the type size of calorie declarations should be no smaller than the name or price, whichever is larger. Another comment stated that the calories for food on display should be permitted to be

displayed in a font that is smaller than the font size of the name of the menu item. (By ''menu item,'' we assume that the comment means the food's name, price, or both.) One comment suggested that the provision be revised to include ''The calorie information on the sign must be readable from the point where consumers are choosing their food, and it must be readily apparent which sign labels which item, both by proximity and by including the name of the product on the sign.''

(Response 127) We disagree that we should require the type size of the calorie declaration for food on display to be no smaller than the type size of the name or price, whichever is larger. All other requirements of this rule that anchor a type size to information already presented to consumers allow a covered establishment to use a type size no smaller than (rather than no larger than) the type size of the information already presented, and the comment provided no basis for why the rule should have a different standard for calorie declarations on signs for food on display and self-service food.

We also disagree that calories for food on display and self-service food should be permitted to be displayed in a font that is smaller than the font size of the name or price of the menu item. Because consumers need to see the name and price to place an order, anchoring the type size of the calorie declaration to the type size of information already on the sign acts, in essence, as an objective and measurable performance standard for whether a disclosure is clear, conspicuous, and prominent. Thus, we do not agree that a smaller type size should be used for the calorie declaration, because doing so would no longer provide for such an objective and measurable performance standard. Therefore, we are retaining the type size requirements for the calorie declaration for food on display and self-service food that are already accompanied by individual signs. However, to be consistent with changes we are making to other provisions of the rule, we have revised § 101.11(b)(2)(iii)(A)(*3*)(*ii*) to provide additional flexibility for the contrasting background of the calorie declaration by permitting the calorie declaration to be in a background at least as contrasting as that used for the name or price of the menu item. We also are making a conforming editorial change to the grammatical construction of the requirement for the color used for the calorie declaration to match the grammatical construction of the revised requirement for the contrasting background used for the calorie declaration. We also are making an editorial correction to insert ''the type size of'' between ''no smaller than'' and ''the name or price.''

No comments suggested specific formatting requirements for calorie declarations when there are no pre-existing signs with the name or price of the food to which the calorie declaration can be anchored. Covered establishments have the flexibility to post the calorie information in a manner that ensures that it is clear, conspicuous, and prominent.

3. Manner of Declaring Calories for Self-Service Beverages

In the proposed rule, we stated that the self-service beverage dispenser itself must have calorie declarations for each flavor or variety offered, such that the calorie declaration is clearly associated with its corresponding flavor or variety (76 FR 19192 at 19216). We received comment on calorie declarations for self-service beverages. After considering these comments, we are adding a new provision to require, for self-service beverages, that calorie declarations be accompanied by the term ''fluid ounces'' and, if applicable, the description of the cup size (*e.g.,* ''small,'' ''medium'').

(Comment 128) A few comments recommended that calories be posted at self-service fountain dispensers for each beverage size offered in the covered establishment. One comment asked us to permit a sign or placard placed adjacent to a fountain beverage machine to separate calorie ranges for specific subcategories, *e.g.,* regular soda, diet soda, milk, coffees, teas, juice by cup size. A few comments recommended that calorie declarations should provide the amount of calories as a range per size.

(Response 128) We agree that calories must be posted at self-service fountain dispensers for each beverage size offered in the covered establishment. As noted previously, section 403(q)(5)(H)(iii) of the FD&C Act requires covered establishments to place adjacent to each standard menu item that is a self-service food or food on display, including self-service beverages, a sign that lists calories per displayed food item or per serving. As already discussed (see section XVII.B), § 101.11(b)(2)(iii)(A) provides several options for where and how a covered establishment could place a sign or placard.

Earlier in this document, we discussed another comment directed to the declaration of calories for self-service beverages (see Comment 126 and Response 126). A self-service standard menu item, including a self-service beverage, is subject to § 101.11(b)(2)(i) (in addition to § 101.11(b)(2)(iii)) when such food is listed on a menu or menu board (see Comment 116 and Response 116). The format requirements for variable menu items in § 101.11(b)(2)(i)(A)(*4*) through (b)(2)(i)(A)(*7*) would apply to calorie declarations on a menu or menu board. Accordingly, to the extent that self-service beverages offered for sale in different flavors or varieties are listed as single menu items on menus or menu boards (*e.g.,* ''soft drinks''), a covered establishment would be required to declare calories on such menus and menu boards for such foods using the same methods applicable to other variable menu items, including ranges, as specified in § 101.11(b)(2)(i)(A)(*4*) through (b)(2)(i)(A)(*8*). However, at the point of self-service, a self-service beverage would be subject to the requirements of section 403(q)(5)(H)(iii) of the FD&C Act and § 101.11(b)(2)(iii). For a standard menu item that is a self-service food, such as a self-service beverage, section 403(q)(5)(H)(iii) of the FD&C Act requires the covered establishment to ''place adjacent to each food offered a sign that lists the calories per displayed food item or per serving.'' Typically, a self-service fountain beverage machine separately dispenses each flavor or variety of beverage from individual valves or dispensers that list the flavor or variety of the beverage (such as orange soda, cola, diet cola), and the consumer can see what beverage flavors and varieties are available. Otherwise, consumers would not be able to determine which flavor or variety of beverage is dispensed from a particular valve or dispenser at the self-service fountain beverage machine. Because these self-service beverages typically are presented in a manner that allows consumers to see each beverage individually, as well as the other beverages available, including other beverages offered in different flavors or varieties, the way in which these standard menu items are offered for sale is not analogous to standard menu items that come in different flavors or varieties but are listed as a single menu item on a menu or menu board. Further, because consumers can see flavor or variety of self-service beverage offered for sale, the consumer should also be able to see the number of calories contained in each flavor or variety offered for sale at the self-service machine. For these reasons, calories must be declared for each specific flavor or type of beverage available at a self-service machine rather than declared as a range.

(Comment 129) A few comments recommended that covered establishment should declare the amount of calories for self-service beverages based on the number of ounces served. A few other comments opposed declaring the number of calories per ounces served. These comments contended that it is more practical to estimate the size of a beverage with a household measure than to guess the ounces without measuring the beverage. The comments maintained that calories per ounce would be confusing. One comment stated that there is not enough space on menus for declaring the number of calories per ounce served.

(Response 129) We disagree that declaring calories based on the volume in fluid ounces for self-service beverages, as required by § 101.11(b)(2)(iii)(A)(*2*)(*iii*) of the final rule, would be overly confusing. Fluid ounces are commonly used to describe the volume of beverages in packaged food sold in the United States and, thus, consumers who purchase beverages likely would be familiar with ''fluid ounces'' in the context of beverages. Further, as discussed previously (see Response 125), § 101.11(b)(2)(iii)(A)(*2*)(*iii*) of the final rule specifies that, for self-service beverages, ''per serving'' means per total number of fluid ounces in the cup in which a self-service beverage is served and, if applicable, the description of the cup size (*e.g.,* ''140 calories per 12 fluid ounces (small)''). As an operational companion to § 101.11(b)(2)(iii)(A)(*2*)(*iii*), we also are establishing in § 101.11(b)(2)(iii)(A)(*3*)(*iii*) of the final rule specific format requirements applicable to the declaration of calories for self-service beverages. Section 101.11(b)(2)(iii)(A)(*3*)(*iii*) of the final rule requires that, for self-service beverages, calorie declarations must be accompanied by the term ''fluid ounces'' and, if applicable, the description of the cup size (*e.g.,* ''small,'' ''medium''). For example, calories could be declared as ''small Orange Fizz (12 fluid ounces)—150 calories.'' Accordingly, the calorie declaration will provide information regarding the number of fluid ounces served, and in some cases, the size of the cup, along with the number of calories. Typically, self-service beverages are offered for sale, including listed or otherwise separated by price, based on size (*e.g.,* ''small—$1.59,'' ''12 ounces—$1.59''), and the sizes are described using general descriptors (*e.g.,* ''small,'' ''medium,'' or ''large,'') or by fluid ounces. Therefore, in such situations, consumers will have further context regarding the number of fluid ounces served in a self-service beverage, and, in some cases, the size of the cup.

F. Applicability of Requirements for Written Nutrition Information, Succinct Statement, and Statement of Availability to Self-Service Foods and Foods on Display

In the proposed rule, we tentatively concluded that covered establishments must provide written nutrition information for self-service foods and foods on display that are standard menu items as required by section 403(q)(5)(H)(ii)(III) of the FD&C Act (76 FR 19192 at 19216).

(Comment 130) One comment argued that applying certain requirements of section 403(q)(5)(H)(ii) of the FD&C Act to self-service food and food on display is not a reasonable construction of the statute, given that calorie disclosure requirements for self-service food and food on display appear ''in a wholly different subclause.'' The comment asserted that because the ''subclause'' (section 403(q)(5)(H)(iii)) of the FD&C Act) does not require additional written nutrition information or a succinct statement concerning suggested daily caloric intake and section 403(q)(5)(H)(ii) of the FD&C Act does, Congress deliberately omitted those requirements from section 403(q)(5)(H)(iii) of the FD&C Act. The comment argued that, given that every word excluded from a statute must be presumed to have been excluded intentionally, it is not permissible to interpret the statute to require covered establishments to provide additional written nutrition information and a succinct statement concerning suggested daily caloric intake for self-service food and food on display.

(Response 130) We agree in part, and disagree in part, with the comment. As we discussed in the proposed rule and Response 116, section 403(q)(5)(H)(i) of the FD&C Act states, ''in the case of food that is a standard menu item . . . [the covered] establishment shall disclose the information described in subclauses (ii) *and* (iii)'' (emphasis added). The word ''and'' between the references to subclauses (ii) and (iii), as opposed to a disjunctive ''or,'' indicates that covered establishments must follow the requirements in subclause (ii) for all standard menu items, as applicable, and subclause (iii) for all standard menu items, as applicable.

We acknowledge that a principle of statutory interpretation is that ''where Congress includes particular language in one section of a statute but omits it in another section of the same [statute], it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'' *Russello* v. *U.S.,* 464 U.S. 16, 23 (1983) (internal citations omitted). We considered this principle when interpreting section 403(q)(5)(H) of the FD&C Act. Section 403(q)(5)(H)(ii)(III) of the FD&C Act—the section requiring additional written nutrition information—omits certain important words. Sections 403(q)(5)(H)(ii)(I), (II), and (IV) of the FD&C Act specify that certain disclosures must appear ''on the menu,'' ''on the menu board,'' and ''on the menu or menu board,'' respectively. Section 403(q)(5)(H)(ii)(III) of the FD&C Act does not mention menus or menu boards at all. Because section 403(q)(5)(H)(i) of the FD&C Act states that covered establishments must disclose the information in section 403(q)(5)(H)(ii) and (iii) of the FD&C Act for standard menu items, it is reasonable to apply section 403(q)(5)(H)(ii)(III) of the FD&C Act to standard menu items, regardless of whether they appear on menus or menu boards. Therefore, the rule requires that covered establishments provide the additional written nutrition information described in section 403(q)(5)(H)(ii)(III) of the FD&C Act for all standard menu items, including self-service food and food on display regardless of whether such standard menu items appear on menus or menu boards.

We agree that the succinct statement concerning suggested daily caloric intake is required only on menus or menu boards, based on the plain language of sections 403(q)(5)(H)(ii)(I)(bb) and 403(q)(5)(H)(ii)(II)(bb) of the FD&C Act. Similarly, the statement of availability of the written nutrition information is only required on menus or menu boards, based on the plain language of section 403(q)(5)(H)(ii)(IV) of the FD&C Act.

We discuss the specific requirements related to the succinct statement and statement of availability for self-service food and food on display in the next section. We discuss the specific requirements related to the written nutrition information for self-service food and food on display in section XVII.H.

G. Succinct Statement and Statement of Availability for Self-Service Foods and Foods on Display

Proposed § 101.11(b)(2)(iii)(B) would require that for food on display identified by a menu (meaning an identifying sign) adjacent to the food itself, the statement that puts the calorie

information in the context of a recommended total daily caloric intake as required by § 101.11(b)(2)(i)(B) and the statement regarding the availability of the additional written nutrition information required by § 101.11(b)(2)(i)(C) must be provided in one of two ways. Proposed § 101.11(b)(2)(iii)(B) would permit these two statements to appear either on the sign adjacent to the standard menu item or on a separate, larger sign, in close proximity to the food on display, that can be easily read as the consumer is making order selections. Proposed § 101.11(b)(2)(iii)(B) would explain that this requirement is satisfied if the two statements appear on a large menu board that can be easily read as the consumer is viewing the food on display.

In the following paragraphs, we discuss comments on this proposed provision. After considering these comments, we have revised the provision to clarify that the requirements to provide the statement that puts the calorie information in the context of a recommended total daily caloric intake (also referred to as the ''succinct statement'') and the statement of availability for foods on display apply to all types of food on display, including those that are self-service. Further, we are also providing further flexibility for how to satisfy those requirements.

(Comment 131) In the proposed rule, we noted that signs identifying food on display placed adjacent to such foods meet the definition of a ''menu'' or ''menu board'' within the meaning of section 403(q)(5)(H)(xi) of the FD&C Act, in that such signs are the primary writings of the establishment from which consumers make order selections (76 FR 19192 at 19217). Further, we noted that, as a result, the requirements to disclose the succinct statement and statement of availability on menus and menu boards under sections 403(q)(5)(H)(ii)(I)(bb), (II)(bb), and (IV) of the FD&C Act would apply to such small signs (76 FR 19192 at 19217). However, we noted that the requirements to post the statements on small signs seem to pose difficulties given the size of such signs, and from a consumer's perspective, it is probably unnecessary for the two statements to appear on every single individual identifying sign.

Taking these issues into consideration, along with the space on small signs that constitute menus and menu boards, as provided in section 403(q)(5)(H)(x) of the FD&C Act, we tentatively concluded that each individual sign could be considered its own menu, but that a set of signs that are in close proximity to each other, such as those that might identify items in a bakery display counter, could be viewed together as the primary writing from which consumers choose among those items to order (76 FR 19192 at 19217). As a result, we proposed in § 101.11(b)(2)(iii)(B) that covered establishments may place the succinct statement and statement of availability on individual specific signs or on a separate, larger sign, in close proximity to food on display, that can be easily read as the consumer is making his or her order selection (76 FR 19192 at 19217). In addition, we tentatively concluded that signs identifying food on display that are the primary writing from which consumers select the corresponding items to order and are in close proximity to the menu board, such that the menu board can be easily read as the consumer is viewing the food on display, could be considered part of that menu board.

One comment asserted that menu boards, tags, and other signs within an establishment are used by consumers to identify standard menu items and make order selections. The comment argued, however, that tags or other signs should not be considered menus or menu boards because a menu board lists multiple items from which a consumer can make an order selection.

One comment argued that if the succinct statement and statement of availability already appeared on a menu board, they should not have to appear again on signs adjacent or in close proximity to self-service foods or foods on display. The comment stated that the final rule should provide that posting the statement of availability and the succinct statement on the menu board of the covered establishment is sufficient to inform consumers who are selecting food on display and self-service food.

(Response 131) We agree that an individual small sign adjacent to a self-service food or food on display that contains the name (or image) and price of a standard menu item, and that can be used by a consumer to make an order selection from the establishment at the time the consumer is viewing the sign would meet the definition of a menu or menu board within the meaning of section 403(q)(5)(H)(xi) of the FD&C Act. As a result, the requirements of sections 403(q)(5)(H)(ii)(I)(bb), (II)(bb), and (IV) of the FD&C Act for a succinct statement and statement of availability apply to such signs. However, as we noted in the proposed rule, the obligation to provide the succinct statement and statement of availability on every individual small sign likely would pose difficulties given the small size of these individual signs, and it likely would not be necessary, from a consumer's perspective, for the two statements to appear on every individual sign (76 FR 19192 at 19217). Considering these factors and the limited space on these individual small signs that constitute menus or menu boards, as described by section 403(q)(5)(H)(x)(II) of the FD&C Act, we conclude that, while each individual sign could be considered its own menu, a set of signs that are in close proximity to each other could also be viewed together as the primary writing from which consumers choose among items in making order selections. Further, we conclude that a covered establishment can satisfy the requirements for posting a succinct statement and statement of availability for self-service foods and foods on display by posting such statements on the individual sign adjacent to the food itself, on a separate, larger sign, in close proximity to the food that can be easily read as the consumer is making an order selection, or on a large menu board that can be easily read as the consumer is ordering the food. Accordingly, we are retaining § 101.11(b)(2)(iii)(B) and making revisions for clarity. We have revised § 101.11(b)(2)(iii)(B) to clarify that the provision applies to food that is self-service or on display and is identified by an individual sign adjacent to the food itself where such sign meets the definition of a menu or menu board under paragraph (a) of this section. As an inadvertent error, proposed § 101.11(b)(2)(iii)(B) opened with the clause ''For food on display'' and did not specifically identify food that is self-service as being covered by the proposed requirements for providing the succinct statement and statement of availability on signs that are menus. As a practical matter, food that is ''self-service'' is ''on display'' and, thus, the requirements apply to ''self-service food'' regardless of whether ''self-service food'' is specified or not. Comments that addressed proposed § 101.11(b)(2)(iii)(B) from the perspective of both food on display and self-service food implicitly acknowledged that self-service foods would be subject to proposed § 101.11(b)(2)(iii)(B). Moreover, § 101.11(b)(2)(iii)(B) is a subparagraph of § 101.11(b)(2)(iii), which establishes requirements for ''food that is self-service or on display.'' For clarity, and to ensure that covered establishments are aware that § 101.11(b)(2)(iii)(B) and the flexibility it provides applies to self-service foods identified by a menu adjacent to the food itself, we have revised the opening clause of

§ 101.11(b)(2)(iii)(B) to read ''For food that is self-service or on display . . .'' We also are making associated edits throughout the provision to remove any narrow reference only to food that is on display.

H. The Written Nutrition Information That Must Be Provided for Food That Is Self-Service or on Display

Proposed § 101.11(b)(2)(iii)(C) would require that the nutrition information in written form required by § 101.11(b)(2)(ii) be provided for food that is self-service or on display, except for packaged food that bears nutrition labeling information required by § 101.9 if the packaged food, including its label, can be examined by a consumer before purchasing the food. In the following paragraphs, we discuss comments on this proposed provision. After considering these comments, we have revised § 101.11(b)(2)(iii)(C) to clarify the regulatory requirements that apply to the nutrition labeling information on the packaged food.

(Comment 132) One comment asked us to provide more detail on what format establishments may use to provide the written nutrition information for foods on display and self-service food to ensure that the information is readily available and easily readable.

(Response 132) Section 101.11(b)(2)(ii) both requires that written nutrition information be available for standard menu items and establishes format requirements for that written nutrition information. With one exception, the format requirements of § 101.11(b)(2)(ii) apply to standard menu items that are self-service food or food on display. See § 101.11(b)(2)(ii) and the discussion of § 101.11(b)(2)(ii) in section XVI. The exception is for packaged foods, insofar as they bear nutrition labeling required by section 403(q)(5)(H)(ii)(III) of the FD&C Act and § 101.11(b)(ii)(2)(D). We discuss this exception further in Response 133.

(Comment 133) Two comments asked us to broaden the exception in § 101.11(b)(2)(iii)(C) for packaged food in compliance with § 101.9, regardless of whether the nutrition information can be examined prior to purchase. One comment pointed out that some packaged confectioneries may be placed near the cash register in a covered establishment. The comment stated that these confectioneries may be exempt from the nutrition labeling requirements of § 101.9 because they have fewer than 12 square inches of available label space or may be in gift packages. This comment stated that if a food is subject to and in compliance with § 101.9, it should not also be subject to § 101.11. The comment maintained that a food should be required to comply with one nutrition labeling regulation or the other, but not both. Another comment stated that some foods, such as food in small packages, foods with insignificant amounts of all the nutrients required on the labels of packaged food (*e.g.,* bottled water) and foods sold in gift packages, which may provide the nutrition information inside the box or package, should be exempt from the menu labeling requirements even though their nutrient content cannot be examined by consumers prior to purchase. The comment also stated that if these foods included front of package labeling, they would lose the exemption from nutrition labeling.

(Response 133) Section 403(q)(5)(H) of the FD&C Act does not establish any new requirements regarding the labels of packaged food. Furthermore, to clarify that the requirements of § 101.11 do not affect the exemptions from nutrition labeling under § 101.9(j)(2) and (j)(3), we proposed conforming amendments to § 101.9(j)(2) and (j)(3). As discussed in the proposed rule, the NLEA amendments to the FD&C Act included an exemption, at sections 403(q)(5)(A)(i) and (ii) of the FD&C Act, for nutrition labeling for food that is ''served in restaurants or other establishments in which food is served for immediate human consumption'' or ''sold for sale or use in such establishments'' (76 FR 19192 at 19193 (citing 21 U.S.C. 343(q)(5)(A)(i)). The NLEA amendments also included an exemption for food of the type described in section 403(q)(5)(A)(i) of the FD&C Act that is primarily processed and prepared in a retail establishment, ready for human consumption, ''offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment.'' (21 U.S.C. 343(q)(5)(A)(ii)). We issued regulations for these exemptions at § 101.9(j)(2) and (j)(3); however, these exemptions were contingent on there being no nutrient content claims or other nutrition information in any context on the labeling or in the labeling or advertising. As discussed in section IV.B, we are finalizing the conforming amendments to § 101.9(j)(2) and (j)(3). Likewise, as discussed in section IV.B, we also have made a conforming amendment to § 101.9(j)(4), which applies to foods that contain insignificant amounts of nutrients and food components required to be included in the declaration on nutrition information under § 101.9(c). As a result, a food that is exempt from the requirements of § 101.9 under § 101.9(j)(2), (j)(3), and (j)(4) would not fall out of such exemption by complying with the requirements of § 101.11. We also note that, for a standard menu item that contains insignificant amounts of all of the nutrients required in § 101.11(b)(2)(ii)(A), including, if applicable, a packaged food, a covered establishment generally would not be required to provide written nutrition information for that standard menu item (see § 101.11(b)(2)(ii)(B)).

Section 101.11 does not change the food label requirements under § 101.9(h)(3) for food products with separately packaged ingredients or foods where a package contains a variety of foods, or an assortment of foods, and is in a form intended to be used as a gift. Similarly, § 101.11 does not change the exception at § 101.9(j)(13)(i) for foods in small packages that have a total surface area of less than 12 square inches of available label space. To the extent that such foods are offered for sale in covered establishments, they generally would fall within the exceptions at § 101.9(j)(2) and (j)(3); when this is the case, the conforming amendments to § 101.9(j)(2) and (j)(3) would preserve the pre-existing exemptions under § 101.9 for such foods.

While section 403(q)(5)(H) of the FD&C Act does not establish any new requirements regarding the labels of packaged food, there may be some situations in which a covered establishment (rather than the manufacturer of a packaged food) must disclose nutrition information for a food on display or a self-service food that is a packaged food, such as a packaged food that is offered for sale at a cash register in a covered establishment. For example, if a standard menu item, such as a package of chips, is on display (*e.g.,* a package of chips that is part of a combination meal or listed individually on a menu or menu board and is available at a cash register), the covered establishment would be required to post a calorie declaration on a sign adjacent to the package of chips and provide written nutrition information for the package of chips unless the label for the chips bears calorie and certain other nutrition information and can be examined by the consumer prior to purchase. Further, the covered establishment would be required to post a calorie declaration for the package of chips on a menu and menu board to the extent the package of chips is listed on such menu and menu board.

In the proposed rule, we tentatively concluded that a packaged food that is self-service or food on display that bears

nutrition information required by section 403(q)(1) of the FD&C Act and § 101.9 satisfies the calorie disclosure requirement for self-service food or food on display in section 403(q)(5)(H)(iii) of the FD&C Act and the written nutrition information requirement of section 403(q)(5)(H)(ii)(III) of the FD&C Act (see 76 FR 19192 at 19217 and 19235). In addition, we tentatively concluded that, in such a situation, a covered establishment would still be required to post calorie declarations on menus and menu boards for packaged foods that are standard menu items and are listed on such menus and menu boards (*e.g.,* where ''chips'' is listed on a menu board and refers to packaged bags of chips that are available as self-service foods or foods on display) (76 FR 19192 at 19217). We affirm these conclusions; however, we have revised the exception at § 101.11(b)(2)(iii)(C).

Under proposed § 101.11(b)(2)(iii)(C), self-service food and food on display would be subject to the written nutrition information requirement of § 101.11(b)(2)(ii), except for packaged food that bears nutrition labeling information required by § 101.9 if the packaged food can be examined by a consumer before purchasing. In response to comments regarding a food that is in compliance with § 101.9 but does not otherwise bear nutrition labeling, we have revised the exception at § 101.11(b)(2)(iii)(C) to clarify in relevant part that a covered establishment is not required to provide the written nutrition information in § 101.11(b)(2)(ii) for a packaged food, insofar as that packaged food bears the nutrition information specified in section 403(q)(5)(H)(ii)(III) of the FD&C Act and the written nutrition information requirements of § 101.11(b)(2)(ii). For example, if the package of chips described previously includes Nutrition Facts information, including the nutrition information specified in section 403(q)(5)(H)(ii)(III) of the FD&C Act and § 101.11(b)(2)(ii), a covered establishment would not be required to provide written nutrition information for the chips as required by § 101.11(b)(2)(ii), provided that the packaged food, including its label, can be examined by a consumer before purchasing the food. However, if the package of chips does not bear the nutrition information specified in section 403(q)(5)(H)(ii)(III) of the FD&C Act and § 101.11(b)(2)(ii) (*e.g.,* because it is exempt from the nutrition label requirements of § 101.9, such as a food in a small package that has fewer than 12 square inches of available label space as provided by § 101.9(j)(13)), the covered establishment would be required to provide written nutrition information for the chips as required by § 101.11(b)(2)(ii). Moreover, if the package of chips does not bear the nutrition information specified in section 403(q)(5)(H)(ii)(III) of the FD&C Act and § 101.11(b)(2)(ii), the food would not satisfy the calorie disclosure requirement for self-service food or food on display in section 403(q)(5)(H)(iii) of the FD&C Act, and the covered establishment would be required to disclose the number of calories contained in the package of chips on a sign adjacent to the food, in accordance with § 101.11(b)(2)(iii). In either situation, the establishment would be required to post a calorie declaration for the package of chips on the menu and menu board to the extent the package of chips is listed on such menu and menu board, as required by § 101.11(b)(2)(i).

XVIII. Comments and FDA Response on Proposed § 101.11(c)(1) to (c)(5)—Determination of Nutrient Content (Final § 101.11(c)(1) to (c)(2))

Under section 403(q)(5)(H)(iv) of the FD&C Act, a covered establishment must have a reasonable basis for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in § 101.10. Proposed § 101.11(c)(1) would establish this reasonable basis requirement in this rule.

In addition, proposed § 101.11(c)(2), (c)(3), (c)(4), and (c)(5) would establish requirements for determining compliance with proposed § 101.11(c)(1). As discussed in the proposed rule, because the nutrition information that is required to be disclosed by covered establishments is a subset of the nutrition information required in § 101.9, we modeled proposed § 101.11(c)(2), (c)(3), (c)(4), and (c)(5) after our regulation for compliance with the nutrition labeling requirements for packaged foods in § 101.9(g) (76 FR 19192 at 19218). In brief, for purposes of compliance, proposed § 101.11(c)(2), (c)(3), (c)(4), and (c)(5) would establish the following:

- Proposed § 101.11(c)(2) would define two classes of nutrients. ''Class I'' nutrients would be ''added'' nutrients and ''Class II'' nutrients would be ''naturally occurring'' (indigenous) nutrients in standard menu items;
- Proposed § 101.11(c)(3) would establish conditions under which a standard menu item with a nutrient declaration of protein, total carbohydrate, or dietary fiber would be deemed to be misbranded under section 403(a) of the FD&C Act, including a requirement that, for Class II protein, total carbohydrate, or dietary fiber, the nutrient content of an appropriate composite of a standard menu item not be less than 80 percent of the declared value;
- Proposed § 101.11(c)(4) would establish conditions under which a standard menu item with a nutrient declaration of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium would be deemed to be misbranded under section 403(a) of the FD&C Act, including a requirement that the nutrient content of an appropriate composite of a standard menu item not be more than 20 percent in excess of the declared value; and
- Proposed § 101.11(c)(5) would allow for reasonable excesses of protein, total carbohydrate, dietary fiber and reasonable deficiencies of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium.

Comments commonly referred to the combined provisions of proposed § 101.11(c)(3) and (c)(4) as ''the 80/120 rule.''

In the following paragraphs, we discuss comments on proposed § 101.11(c)(1), (c)(2), (c)(3), (c)(4), and (c)(5). After considering these comments, we are:

- Finalizing § 101.11(c)(1) with several changes and making a companion change to the substantiation requirements of proposed § 101.11(c)(6) (which is being established in § 101.11(c)(3));
- Replacing proposed § 101.11(c)(2), (c)(3), (c)(4), and(c)(5) with a new § 101.11(c)(2); and
- Establishing revised certification requirements (in § 101.11(c)(3)(i)(G), (c)(3)(ii)(D), (c)(3)(iii)(E), and (c)(4)(iv)(E)) directed to reasonable steps that a covered establishment takes to ensure that the method of preparation (*e.g.,* types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which the nutrient values were determined.

(Comment 134) One comment asserted that the menu labeling requirements would have an impact on the manufacturers of foods sold to covered establishments, because covered establishments would look to the food manufacturers to supply them with the nutrition information that the covered establishments must provide to consumers. For the most part, food manufacturers do not currently provide restaurants and similar retail food establishments with this information. The comment maintained that some manufacturers may elect to provide the nutrition information in inserts and

other forms of labeling, which will require development of guidelines on how the nutrition information should be provided to restaurant customers.

One comment asked us to consider nutritional information provided by a producer to a covered establishment to be a reasonable basis for the covered establishment's nutrition declarations. Another comment maintained that because food suppliers are not required to provide nutrition information to retailers, compliance with the rule will be challenging for covered establishments. The comment asked us to consider requiring suppliers to provide nutrition information to covered establishments.

(Response 134) The nutrition labeling provisions of this rule only apply to covered establishments as specified in § 101.11(a). Section 4205 of the ACA does not require distributors of food sold to covered establishments to provide nutrition information to those establishments. In addition, section 4205 of the ACA did not remove or amend section 403(q)(5)(G) of the FD&C Act, which provides that the nutrition labeling requirements of section 403(q)(1) through (4) of the FD&C Act do not apply to ''food which is sold by a food distributor if the distributor principally sells food to restaurants and other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells.'' Accordingly, this rule does not require distributors of food sold to covered establishments to provide nutrition information to covered establishments. Nevertheless, we have revised § 101.11(c)(1), in relevant part, to expressly specify that the use of Nutrition Facts on labels on packaged foods that comply with the nutrition labeling requirements of section 403(q)(1) of the FD&C Act and § 101.9 is an additional means that may be used as a reasonable basis to determine nutrient values.

We encourage cooperation between food distributors and covered establishments so that covered establishments are able to efficiently comply with the requirements of this rule. We would consider nutrition information otherwise provided by food distributors to covered establishments for food sold by such distributors to be captured within the provision that nutrient values may be determined by using ''other reasonable means'' provided that such nutrition information is truthful and not misleading and otherwise in compliance with the requirements of sections 403(a)(1) and (q)(5)(H) of the FD&C Act and § 101.11.

We also have revised § 101.11(c)(1) to include another example of ''other reasonable means''—*i.e.,* FDA nutrient values for raw fruits and vegetables in Appendix C of part 101 and FDA nutrient values for cooked fish in Appendix D of part 101. We developed this nutrition information to encourage retail stores that sell raw fruits, vegetables, and cooked fish to participate in the voluntary point-of-purchase nutrition program (§§ 101.42 through 101.45).

(Comment 135) Many comments agreed that a covered establishment must have a reasonable basis for its nutrient content disclosures and the means for determining them, which include nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in § 101.10. Some comments suggested that we replace the language in proposed § 101.11(c) with the language in § 101.13(q)(5)(ii). Section 101.13(q)(5) sets forth requirements for nutrient content claims for food served in restaurants or other establishments in which food is served for immediate consumption or which is sold for sale or use in such establishments. Section 101.13(q)(5)(ii) provides that for nutrient content claims made for such food, in lieu of analytical testing, compliance may be determined using a reasonable basis for concluding that the food that bears the claim meets the definition for the claim. It continues by stating that this reasonable basis may derive from recognized databases for raw and processed foods, recipes, and other means to compute nutrient levels in the foods or meals and may be used provided reasonable steps are taken to ensure that the method of preparation adheres to the factors on which the reasonable basis was determined (*e.g.,* types and amounts of ingredients, cooking temperatures). Furthermore, according to § 101.13(q)(5)(ii), firms making claims on foods based on this reasonable basis criterion are required to provide to appropriate regulatory officials on request the specific information on which their determination is based and reasonable assurance of operational adherence to the preparation methods or other basis for the claim.

(Response 135) We agree that some aspects of § 101.13(c)(5)(ii) that we did not include in § 101.11(c) should be added to the rule. In particular, § 101.13(c)(5)(ii) requires that reasonable steps be taken to ensure that the method of preparation adheres to the factors on which the reasonable basis was determined (*e.g.,* types and amounts of ingredients, cooking temperatures) when the reasonable basis for a nutrient disclosure is derived using databases for raw and processed foods, recipes, or other means (*e.g.,* means other than analytical testing). As discussed later in this document (see Comment 136), several comments opposed our proposal for using a compliance approach for determining compliance modeled after § 101.9(g) and some comments discussed the problems that can occur when the preparation of a menu item does not adhere to a recipe or deviates from the parameters used as the reasonable basis. In Response 136, we discuss the provisions of § 101.11(c)(2) that we are establishing in this rule in lieu of the provisions of proposed § 101.11(c)(2), (c)(3), (c)(4), and (c)(5) that were modeled after § 101.9(g). Those new provisions specify, in relevant part, that a covered establishment must take reasonable steps to ensure that the method of preparation (*e.g.,* types and amounts of ingredients, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

We also agree that § 101.11(c) should require, among other things, that a covered establishment provide to FDA on request specific information about the basis for its nutrient declarations and reasonable assurance of operational adherence to the preparation methods used as the basis for its nutrient declarations. As discussed in Response 136, we have revised the rule to establish these requirements.

We disagree that § 101.11(c) need specify that a reasonable basis may derive from recognized databases for raw and processed foods, recipes, and other means to compute nutrient levels in the foods or meals ''in lieu of analytical testing.'' Proposed § 101.11(c)(1) already provides for the use of databases, cookbooks, and ''other reasonable means'' in addition to analytical testing. However, we acknowledge that this may not have been clear in part because we used the conjunction ''and'' in proposed § 101.11(c)(1). To make clear that any of the listed means for determining nutrient content may be used, we have revised § 101.11(c)(1) to replace the conjunction ''and'' with the conjunction ''or'' in the second sentence.

As a companion change, we have revised proposed § 101.11(c)(6)(iv)(A) (which is renumbered as § 101.11(c)(3)(iv)(A) in the final rule), which addresses the information that must be provided to FDA, within a reasonable period of time upon request,

when ''other reasonable means are used to provide the nutrition information.'' To emphasize that ''other reasonable means'' does not require analytical testing, § 101.11(c)(3)(iv)(A)) now requires a detailed description of the ''means'' (rather than the ''method'') used to determine the nutrition information.

We are finalizing § 101.11(c)(1) with the following additional changes:

- We are substituting the term ''nutrient declarations'' for the term ''nutrient disclosures'' for consistency in terms used throughout § 101.11. For example, § 101.11(b)(2)(i)(A) establishes requirements to ''declare'' calories, and § 101.11(b)(2)(i)(A)(*3*) refers to calorie ''declarations.''
- We are clarifying that nutrient databases may be used to determine nutrient values regardless of whether they use computer software programs. For example, a covered establishment may use a nutrient database that both lists nutrient values for certain food items and provides software that a covered establishment could use to calculate nutrient values for a standard menu item prepared with several of the listed foods in varying amounts. Alternatively, a covered establishment may use a nutrient database that lists nutrient values for certain food items, but does not provide such software. In such a circumstance, a covered establishment would perform and document its own calculations.
- We are substituting the term ''nutrient values'' for the proposed term ''nutrient levels.'' We are making this change throughout § 101.11(c), as well as throughout the rule, to consistently use the single term ''nutrient values.''
- We are deleting ''as described in § 101.10.'' Section 403(q)(5)(H)(iv) of the FD&C Act provides that a restaurant or similar retail food establishment shall have a reasonable basis for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in 21 CFR 101.10 (or any successor regulation) or in a related FDA guidance. Section 101.10 requires nutrition labeling for a restaurant food that bears a nutrient content or health claim, except that information on the nutrient amounts that are the basis for the claim may serve as the functional equivalent of complete nutrition information. Under § 101.10, nutrient levels may be determined by nutrient databases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. In this rule, § 101.11(c)(1) is patterned after § 101.10, as required by section 403(q)(5)(H)(iv) of the FD&C Act, in that it provides for nutrient values to be determined by nutrient databases, cookbooks, or analyses or by other reasonable bases. However, given that we incorporated the applicable regulatory text from § 101.10 into § 101.11(c)(1), there is no need to refer to § 101.10 within § 101.11(c)(1). Indeed, including ''as described in § 101.10'' within § 101.11(c)(1) could mistakenly signal, to both covered establishments and investigators who would evaluate compliance with this rule, that a covered establishment must look to § 101.10 to determine how to fully comply with § 101.11(c)(1).

As finalized, § 101.11(c)(1) states that a covered establishment must have a reasonable basis for its nutrient declarations. Nutrient values may be determined by using nutrient databases (with or without computer software programs), cookbooks, laboratory analyses, or other reasonable means, including the use of Nutrition Facts on labels on packaged foods that comply with the nutrition labeling requirements of section 403(q)(1) of the FD&C Act and § 101.9, FDA nutrient values for raw fruits and vegetables in Appendix C of part 101 of the chapter, or FDA nutrient values for cooked fish in Appendix D of part 101 of the chapter.

(Comment 136) One comment agreed with our proposal for using an approach for determining compliance modeled after § 101.9(g). The comment recognized that the proposed approach is consistent with the accuracy standards for Nutrition Facts information and stated that even relatively small variances can be significant in influencing cardiovascular health.

The majority of comments opposed our proposal for using an approach for determining compliance modeled after § 101.9(g), particularly with respect to using the ''80/120 rule'' for compliance purposes. Some comments maintained that the proposed criteria for compliance modeled after § 101.9(g) are not consistent with § 101.10. Some comments stated that use of the ''80/120 rule'' for determining compliance with the menu labeling requirements of section 403(q)(5)(H) of the FD&C Act contradicts 20 years of FDA precedence regarding determining compliance for nutrient content claims made for restaurant foods. The comments referred to our statements in the final rule establishing § 101.10 regarding claims for restaurant food (58 FR 2302 at 2387, January 6, 1993) and in our 2008 guidance for restaurant food (Ref. 10). Based on these statements, the comments asserted that we understood the difficulty in determining compliance for restaurant foods making nutrient content claims or health claims and acknowledged the variations unique to restaurant foods (*e.g.,* by recognizing that restaurant foods are generally hand assembled and, therefore, subject to individual product variation), and therefore did not require that restaurants conduct nutrient analyses for such claims. The comments asserted that reasons such as these led us to require in § 101.10 that restaurants have a reasonable basis for making a nutrient content or health claim, and that the proposed rule did not provide any factual basis or evidence that the circumstances that justified the original ''reasonable basis standard'' have changed.

Some comments asserted that using the ''80/120 rule'' for determining compliance with the menu labeling requirements of section 403(q)(5)(H) of the FD&C Act was not the intent of Congress. Some comments considered that use of the ''80/120 rule'' would make the reasonable basis statutory provision at section 403(q)(5)(H)(iv) of the FD&C Act irrelevant. Some comments asserted that use of the ''80/120 rule'' in the proposed rule contradicts the plain language of section 403(q)(5)(H)(iv) of the FD&C Act, and therefore, violates the Administrative Procedure Act (APA). One comment asserted that section 4205 of the ACA proposes a specific standard at section 403(q)(5)(H)(iv) of the FD&C Act for determining nutrient content disclosures under section 4205, and such a specific standard ''does not permit an agency to impose a more rigorous standard than one required by Congress.'' The comment stated that under the framework articulated in *Chevron, U.S.A., Inc.* v. *Natural Resource Defense Counsel,* 467 U.S. 837 (1984), ''courts ask as the threshold question of 'whether Congress has directly spoken to the precise question at issue,'' and ''[i]f the intent of Congress is clear, that is the end of the matter.'' The comment stated that section 4205 of the ACA is unambiguous ''in adopting the pre-existing reasonable basis standard'' in § 101.10 to determine compliance with the nutrition labeling requirements of section 4205, and ''this reflects a clear directive to FDA which does not contemplate, nor permit, any deviation of the kind contemplated in the proposed rule.''

Some comments asserted that Congress expressly directed us to consider ''standardization of recipes and methods of preparation, reasonable variation in serving size and

formulation of menu items . . . inadvertent human error, training of food service workers, variations in ingredients, and other factors'' in issuing regulations to implement section 4205 of the ACA, including those regarding reasonable basis. The comments maintained that by including this language in section 403(q)(5)(H)(x) of the FD&C Act and directing us to consider such factors, Congress demonstrated its familiarity with the challenges involved in requiring nutrition labeling for restaurant food, identifying many of the same factors that led us to implement the reasonable basis standard in § 101.10.

Some comments maintained that it is not practical to require a compliance standard for covered establishments that is the same as had been developed for packaged food manufacturers that use modern manufacturing calibrated equipment and methods for which the ''80/120 rule'' is appropriate. Some comments asserted that restaurant food is not standardized like packaged food. For example, some comments explained that the mere addition of five to seven extra French fries in an order of small fries would increase calories more than 20 percent and make the food product misbranded under the ''80/120 rule.'' The comment stated, as an example, that cheese sticking together and an extra squirt of mayonnaise in a food are not negligent practices, but would make the nutrient content declaration for the food out of compliance. Another comment stated that if a lobster tail is 6 ounces rather than 5 ounces, the calories would be 20 percent higher. Some comments asserted that using the ''80/120 rule'' for compliance is impractical and will require frequent analysis that will add costs. Some comments contrasted manufacturers that test for nutrient variations at a single point or a handful of points of manufacture with restaurants that have thousands of points of manufacture, each of which would require separate analysis. One comment asserted that the ''80/120 standard'' was not practicable and is inflexible for covered establishments and would create increased and unnecessary compliance and litigation costs for covered establishments.

One comment asked us to provide flexibility for variations in portion size and recipes and allow for disparities between the amount of a food used to calculate the calories and the actual size that might be served to or taken by customers. This comment recommended that the final rule create specific guidelines for displaying caloric information for non-uniform menu items (*e.g.* fresh fruit or pieces of chicken).

Some comments pointed to the variability in the nutrient content of restaurant foods based on changes in ingredients and recipes, and seasonal changes in the ingredients as reasons for why complying with the ''80/120 rule'' would be difficult. One comment noted that moisture leaves hot foods at hot-food bars after a certain period of time and as a result nutrient values for such foods change from those values listed in recipe books. The comment asked us to expand the tolerance by 10 percent at both ends if we kept compliance requirements similar to the ''80/120 rule'' rather than a more flexible ''reasonable basis'' standard. Some comments pointed out that there is variability in menu items due to using locally grown ingredients and that the nutrient content of these ingredients can vary by region. One comment asserted that if we do not account for this variation in the final rule, it will be a disincentive to covered establishments to use local farmers and suppliers.

One comment asserted that use of the ''80/120 rule'' will discourage voluntary opting in by restaurants and similar retail food establishments not covered by section 403(q)(5)(H) of the FD&C Act, which would lead to less national uniformity. The comment stated that many State and local restaurant menu labeling laws measure compliance using a standard akin to ''the Federal reasonable basis standard'' and even where no State nutrition labeling laws apply, a restaurant making nutrient content claims would be subject to the ''reasonable basis standard'' under 21 U.S.C. 343(r) (*i.e.,* § 101.10). Therefore, according to the comment, under the proposed rule, small-chain restaurants voluntarily registering with us to be subject to the Federal requirements would subject themselves to more potential liability under the ''Federal 80/120 standard'' and would thus be less likely to voluntarily participate in the Federal menu labeling scheme. The comment maintained that in turn, there would be less national uniformity in menu labeling, consumers would see less consistent nutrition information on menus, and State and local inspectors would have to apply a more complex patchwork of regulatory schemes.

One comment asserted that the ''80/120 rule'' imposes a stricter compliance standard for foods with smaller amounts of a particular nutrient that should be consumed in limited quantities (*e.g.,* fat and cholesterol) because the ''80/120 rule'' measures compliance as a percentage of the declared nutrient levels. For example, a deviation of 1 gram of fat in a salad declared to have 3 grams of fat would make the covered establishment out of compliance. The comment asserted that this is a disincentive for low fat, low sodium foods and is contrary to the purpose of the rule.

One comment recommended that the amount of protein, total carbohydrates, and dietary fiber contained in an appropriate composite of a standard menu item be equal to the declared value, not at least 80 percent of the declared value.

(Response 136) Proposed § 101.11(c)(2), (c)(3), (c)(4), and (c)(5) were modeled after § 101.9(g), including use of the ''80/120 rule.'' Based on what the comments said, we believe that some comments misinterpreted the proposed rule as requiring covered establishments to determine nutrition information through laboratory analyses only. We did not intend to suggest such a limited requirement. Laboratory analysis was merely one of several options we proposed to establish in § 101.11(c)(1) to satisfy the requirement for a reasonable basis for nutrient levels. Instead, proposed § 101.11(c)(2), (c)(3), (c)(4), and (c)(5), were provisions modeled after § 101.9(g), including use of the ''80/120 rule,'' explaining how we would determine whether a covered establishment is in compliance with the requirement (in proposed § 101.11(c)(1)) for a covered establishment to have a reasonable basis for its nutrient disclosures. We did not intend for proposed § 101.11(c)(2), (c)(3), (c)(4), and (c)(5) to require a covered establishment to use laboratory analyses in all circumstances to determine nutrition information for standard menu items. A covered establishment would have been free to choose any reasonable basis so long as it produced accurate results.

While we do not agree with some of the comments, particularly those asserting that our proposal to use the ''80/120 rule'' to determine compliance would violate the APA, we agree that using the ''80/120 rule'' for determining compliance with the nutrition labeling requirements likely would raise practical problems such as some of those described in the comments. Given these practical problems, we have replaced proposed § 101.11(c)(2), (c)(3), (c)(4), and (c)(5) with other requirements in a new § 101.11(c)(2). First, § 101.11(c)(2) specifies that nutrient declarations for standard menu items must be accurate and consistent with the specific basis used to determine nutrient values. For example, for a nutrient declaration to be accurate, a covered establishment that relies on a

nutrient database for a list of nutrient values, and then uses those nutrient values to perform its own calculation of the nutrient values in a standard menu item, must correctly add the nutrient values for all ingredients in the standard menu item taking into consideration the recipe and ingredient amounts used to prepare the standard menu item among other factors. Second, § 101.11(c)(2) also specifies that a covered establishment must take reasonable steps to ensure that the method of preparation (*e.g.,* types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined. Accordingly, under § 101.11(c)(2), a covered establishment that selects a recipe from a cookbook and relies on the cookbook's nutrition information for such recipe as a basis for the establishment's nutrient declarations must take reasonable steps to ensure that employees who prepare the standard menu item do not depart from that recipe, including the recipe's instructions and ingredient amounts. For example, if a covered establishment determines nutrition information for a turkey sandwich based on a recipe along with nutrition information provided in a cookbook for the turkey sandwich, and the recipe specifies using one tablespoon of mayonnaise, the establishment must take reasonable steps to ensure that its employees use one tablespoon of mayonnaise when preparing the turkey sandwich—*e.g.,* through appropriate instruction about the importance of the consistent application of one tablespoon of mayonnaise to satisfy the requirements of this rule.

Although we recognize inadvertent human error and variations in ingredients, covered establishments must ensure that the nutrient declarations are truthful and not misleading in part by having standard methods of preparation for standard menu items and taking reasonable steps to ensure that the methods of preparation used for a standard menu item adhere to the factors on which the nutrient levels were determined. To make clear that a covered establishment has this responsibility, we are also replacing each of the proposed requirements (in proposed § 101.11(c)(6)(i)(H), (c)(6)(ii)(D), (c)(6)(iii)(D), and (c)(6)(iv)(E)) for a certification statement regarding the recipe used to prepare the standard menu item with a requirement for a statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.,* types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined. These provisions are in § 101.11(c)(3)(i)(G), (c)(3)(ii)(D), (c)(3)(iii)(E), and (c)(3)(iv)(E) of the final rule. (See the discussion of these provisions in section XIX.)

We acknowledge that the calorie content of non-uniform menu items such as whole fresh fruit and pieces of chicken vary depending on the size and, in some cases composition (*e.g.,* chicken breast, thigh, or drumstick) of the items. A covered establishment may take such variation into consideration when determining the calorie content and calorie declaration for the menu item. For example, a covered establishment could base its nutrient declarations on the average size of a piece of fruit, or on a weighted average of nutrient values for a box of chicken that contains a fixed number of chicken breasts, thighs, or drumsticks.

In assessing compliance with § 101.11(c), we will consider the factors and criteria specified in both § 101.11(c)(1) and (c)(2), including whether the establishment took reasonable steps to ensure that the method of preparation for a standard menu item adheres to the factors on which the reasonable basis was determined. We will assess compliance on a case by case basis, taking into consideration a number of factors, including the covered establishment's nutrition labeling, the method (*e.g.,* laboratory analysis, nutrient database, cookbook, or nutrient information provided on the labels of packaged food) used by the covered establishment to determine nutrition information, and the steps taken by the establishment to ensure that the method of preparation and amount of a standard menu item adhered to the factors on which its nutrient values were determined. Further, we may conduct our own analysis, including laboratory analysis, as needed, including if we find that nutrient declarations appear to be false or misleading or the basis upon which the covered establishment based its nutrient declaration appears to be unreasonable or is otherwise questionable.

XIX. Comments and FDA Response on Proposed § 101.11(c)(6)—Substantiation Documentation (Final § 101.11(c)(3))

Proposed § 101.11(c)(6) would require that a restaurant or similar retail food establishment provide to FDA, within a reasonable period of time upon request, information substantiating nutrient values including the method and data used to derive these nutrient levels. Proposed § 101.11(c)(6) would require that covered establishments provide the following information:

- For nutrient databases:
  - The identity of the database used.
  - The recipe or formula used as a basis for the nutrient declarations. The recipe posted on the database must be identical to that used by the restaurant or similar retail food establishment to prepare the menu item.
  - For the specified amounts of each ingredient identified in the recipe, a detailed listing (*e.g.,* printout) of the amount of each nutrient that that ingredient contributes to the menu item.
  - If this information is not available because the nutrition information was derived from a computer program, which is designed to provide only a final list of nutrient values for the recipe, a certificate of validation attesting to the accuracy of the computer program.
  - A detailed listing (*e.g.,* printout) of the nutrient values determined for each menu item.
  - If this information is not derived through the aid of a computer program which provides a final nutrient analysis for the menu item, worksheets used to determine the nutrient values for each of these menu items.
  - Any other information pertinent to the final nutrient levels of the menu item (*e.g.,* information about what might cause slight variations in the nutrient profile such as moisture variations).
  - A statement signed by a responsible individual employed by the covered establishment that can certify that the information contained in the nutrient analysis is complete and accurate and that the recipe used to prepare the menu item is identical to that used for the nutrient analysis.
- For published cookbooks that contain nutritional information for recipes in the cookbook:
  - The name, author, and publisher of the cookbook used.
  - If available, information provided by the cookbook about how the nutrition information for the recipes was obtained.
  - A copy of the recipe used to prepare the menu item and a copy of the nutrition information for that menu item as provided by the cookbook.

○ A statement signed by a responsible individual employed by the covered establishment certifying that the recipe used to prepare the menu item by the restaurant or similar retail food establishment is the same recipe provided in the cookbook. (Recipes may be divided as necessary to accommodate differences in the portion size derived from the recipe and that are served as the menu item but no changes may be made to the proportion of ingredients used.).

• For analyses:

○ A copy of the recipe for the menu item used for the nutrient analysis.

○ The identity of the laboratory performing the analysis.

○ Copies of analytical worksheets used to determine and verify nutrition information.

○ A statement signed by a responsible individual employed by the covered establishment that can certify that the information contained in the nutrient analysis is complete and accurate and an additional signed statement certifying that the recipe used to prepare the menu item is identical to that used for the nutrient analysis.

• For nutrition information provided by other reasonable means:

○ A detailed description of the method used to determine the nutrition information.

○ Documentation of the validity of that method.

○ A recipe or formula used as a basis for the nutrient determination. The recipe used in determining these nutrient values must be the same recipe used by the restaurant and similar retail food establishment to prepare the item.

○ Any data derived in determining the nutrient values for the menu item; and

○ A statement signed by a responsible individual employed by the covered establishment that can certify that the information contained in the nutrient analysis is complete and accurate and that the recipe used to prepare the menu item is identical to that used for the nutrient analysis.

In the following paragraphs, we discuss comments on the proposed substantiation requirements. After considering comments, including comments (discussed in the previous section of this document) that caused us to remove proposed § 101.11(c)(2), (c)(3), (c)(4), and (c)(5), we are:

• Redesignating proposed § 101.11(c)(6) as § 101.11(c)(3);

• Clarifying the applicability of the requirements by replacing the term ''restaurant or similar retail food establishment'' with ''covered establishment'' in the introductory paragraph in § 101.11(c)(3) and in the subparagraph in § 101.11(c)(3)(ii)(D).

• Providing that the statement certifying that the information contained in the nutrient analysis is complete and accurate may be signed by a responsible individual employed by ''the covered establishment or its parent entity'' (proposed § 101.11(c)(6)(i)(H), (c)(6)(iii)(D), and (c)(6)(iv)(E), redesignated as § 101.11(c)(3)(i)(F), (c)(3)(iii)(D), and (c)(6)(iv)(D), respectively);

• Requiring a certification that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.,* types and amounts of ingredients, cooking temperatures in the recipe) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined;

• Requiring that all certification statements be dated as well as signed;

• Specifying what we mean by ''the identity of the database used'' in proposed § 101.11(c)(6)(i)(A) (redesignated as § 101.11(c)(3)(i)(A));

• Combining and replacing certain proposed details of the substantiation documentation when nutrient databases are used (*i.e.,* proposed § 101.11(c)(6)(i)(C), (c)(6)(i)(D), and (c)(6)(i)(F)) with requirements (in § 101.11(c)(3)(i)(C)) to present the requirements in a simplified and streamlined format;

• Specifying what we mean by ''the identity of the laboratory performing the analysis'' in proposed § 101.11(c)(6)(iii)(B) (redesignated as § 101.11(c)(3)(iii)(B));

• Specifying that copies of analytical worksheets used to determine and verify nutrition information must include the analytical method in proposed § 101.11(c)(6)(iii)(C) (redesignated as § 101.11(c)(3)(iii)(C));

• Revising proposed § 101.11(c)(6)(iv)(A) (redesignated as § 101.11(c)(3)(iv)(A)) to require a detailed description of the ''means'' (rather than the ''method'') used to determine the nutrition information ''by other reasonable means'';

• Deleting proposed § 101.11(c)(6)(iv)(B) and redesignating proposed § 101.11(c)(6)(iv)(C), (c)(6)(iv)(D) and (c)(6)(iv)(E) as § 101.11(c)(3)(iv)(B), (c)(3)(iv)(C), and (c)(3)(iv)(D), respectively; and

• Revising proposed § 101.11(c)(6)(iv)(D) (redesignated as § 101.11(c)(3)(iv)(C)) to provide an example of any ''data derived in determining the nutrient values.''

In addition, as nonsubstantive editorial changes we are:

• Replacing all instances of the term ''nutrient levels'' with the term ''nutrient values'' to consistently use the same term throughout § 101.11(c);

• Replacing all instances of the term ''menu item'' with ''standard menu item'' to emphasize that the requirements for determination of nutrient content apply only to standard menu items; and

• Adding the conjunction ''and'' between § 101.11(c)(3)(i)(F) and § 101.11(c)(3)(i)(G), between § 101.11(c)(3)(ii)(C) and § 101.11(c)(3)(ii)(D), between § 101.11(c)(3)(iii)(D) and § 101.11(c)(3)(iii)(E), and between § 101.11(c)(3)(iv)(D) and § 101.11(c)(3)(iv)(E), to clarify that all of the items listed under § 101.11(c)(3)(i), § 101.11(c)(3)(ii), § 101.11(c)(3)(iii), and § 101.11(c)(3)(iv) are required.

(Comment 137) As discussed in more detail in section XVIII (see Comment 136), several comments opposed the nutrient determination requirements in proposed § 101.11(c)(2), (c)(3), (c)(4), and (c)(5).

(Response 137) As discussed in more detail in section XVIII (see Response 136), we are deleting those requirements from the rule. Some comments misinterpreted these provisions, *e.g.,* by concluding that we intended to require the use of laboratory analysis as a reasonable basis in all circumstances. To reduce the potential for future misunderstanding about the substantiation provisions in the final rule, we have made the following revisions to the requirements for substantiation documentation.

First, we have revised proposed § 101.11(c)(6)(iii) (redesignated as § 101.11(c)(3)(iii) in the final rule) to clarify that the analyses governed by the provision are ''laboratory analyses.'' Some of the specific requirements of § 101.11(c)(3)(iii)) (such as for analytical worksheets) may not apply to other means used by a covered establishment as a reasonable basis for its nutrient determinations.

Second, we are providing more specific information about the requirements for substantiation information. Specifically:

• We have revised proposed § 101.11(c)(6)(i)(A) (redesignated as § 101.11(c)(3)(i)(A) in the final rule) to specify that substantiation documentation for nutrient databases must include the name and version (including the date of the version) of the database, and, as applicable, the name of the applicable software company and any Web site address for the database. The name and version of a database would include the name and version of

the computer software, if applicable. Any database suitable for use as a reasonable basis for the purposes of § 101.11 would have a name and version number; in some cases, the version number is a date. The version number is necessary to fully identify a database because databases may be updated to reflect more recent data and information, and nutrient values generated with one version of a database may be different from nutrient values generated by a different database. If, for example, a covered establishment used ''version x'' of a database for its nutrient determinations, and we used ''version y'' of that database to evaluate compliance with the nutrient determination requirements of rule, we inadvertently could conclude that the covered establishment is out of compliance with the rule if the nutrient values we obtained using ''version y'' do not match those obtained using ''version x.'' Some databases may be provided by a public source (such as USDA), whereas others may be provided by a private vendor. If we have any questions about the database, we may need to contact the public source or private vendor. Some databases are available on the Internet; the Web site address would enable us to obtain any necessary followup information on an Internet-based database.

- We have revised proposed § 101.11(c)(6)(iii)(B) (redesignated as § 101.11(c)(3)(iii)(B) in the final rule) to specify that substantiation documentation for laboratory analyses must include the name and address of the laboratory. Some laboratories that conduct nutrient analyses have more than one facility, and the name of the laboratory alone would not be sufficient to identify the laboratory that conducted the analysis.
- We have revised proposed § 101.11(c)(6)(iv)(D) (redesignated as § 101.11(c)(3)(iv)(C) in the final rule) to provide ''nutrition information about the ingredients used, including the source of the nutrient information'' as an example of what we mean by any ''data derived in determining nutrient values.''

Third, we are reorganizing and combining the provisions of proposed § 101.11(c)(6)(i)(C), (c)(6)(i)(D), and (c)(6)(i)(F) (in § 101.11(c)(3)(i)(C)) to simplify the requirements and make them more clear. In particular, we reorganized the requirements to clarify that the substantiation documentation that would be provided to FDA can vary depending on characteristics of the database. For example, in some cases, the information and calculations provided by a database are transparent to a person using the database, whereas, in other cases, such information and calculations are not transparent to the user. Section § 101.11(c)(3)(i)(C) addresses these different situations in separate subparagraphs (*i.e.,* in § 101.11(c)(3)(i)(C)(*1*) and (c)(3)(i)(C)(*2*)). Under § 101.11(c)(3)(i)(C)(*1*), the substantiation information for nutrient databases must include information on: (1) The amount of each nutrient that the specified amount of each ingredient identified in the recipe contributes to the menu item; and (2) How the database was used including calculations or operations (*e.g.,* worksheets or computer printouts) to determine the nutrient values for the standard menu items. Under § 101.11(c)(3)(i)(C)(*2*), if the information in § 101.11(c)(3)(i)(C)(*1*) is not available, the substantiation documentation for nutrient databases must include certification attesting that the database will provide accurate results when used appropriately and that the database was used in accordance with its instructions.

Fourth, we have revised proposed § 101.11(c)(6)(iii)(C) (redesignated as § 101.11(c)(3)(iii)(C) in the final rule) to specify that copies of analytical worksheets used to determine and verify nutrition information must include the analytical method used to determine and verify nutrition information. An analytical worksheet cannot be evaluated for compliance purposes unless the method is identified. A key aspect of evaluating analytical results is determining whether the procedure was carried out correctly, by comparing the data in the work sheets to the procedure in the applicable analytical method.

(Comment 138) One comment recommended that covered establishments provide references for their nutrient values to consumers on request. Another comment recommended that establishments be required to maintain the reasonable basis verification only at headquarters, ''and not in-store and available upon customer request or online.'' This comment considered that providing hard copies on site at many locations would be costly, administratively burdensome, and environmentally unsustainable.

(Response 138) We did not propose to require that the substantiation documentation be available to consumers in a covered establishment or online. The provisions for making substantiation documentation available to us were directed to our enforcement of the rule rather than to informing consumers. Hard copies of the substantiation documentation would only need to be provided to FDA ''within a reasonable period of time upon request.'' Thus, a covered establishment need not generate any hard copies of the substantiation information until we request the information. We would request substantiation documentation from individual covered establishments during inspections. However, a covered establishment could wait to physically obtain substantiation documentation generated by its corporate headquarters or parent entity until we ask for it, provided that the covered establishment can obtain the information within a reasonable period of time.

(Comment 139) One comment stated that it was unclear whether each independently operated unit, including a franchisee, will have to substantiate the accuracy of the nutrient information. Some comments disagreed that the responsible person of the covered establishment needs to sign a statement certifying that the nutrient analysis is complete and accurate and that recipes used to prepare menu items are identical to those used for the nutrient analysis. The comments asserted that this information is mostly gathered at corporate headquarters and there is no comparable requirement for packaged food.

(Response 139) We agree, in part, and disagree, in part, with these comments. We agree that the responsible individual certifying that the nutrient analysis is complete and accurate need not be employed at the covered establishment; instead, the individual could be employed at the establishment's corporate headquarters or parent entity. Whether such individual is employed at the covered establishment or the establishment's corporate headquarters or parent entity, it is critical that the individual who signs the certification has a factual basis for certifying that the nutrient analysis is complete and correct.

We disagree that a responsible individual employed at the covered establishment's corporate headquarters or parent entity, rather than a responsible individual employed at the covered establishment, could sign a certification regarding the use of a recipe within a covered establishment. A responsible individual employed at the establishment's corporate headquarters or parent entity likely would not have a factual basis for certifying the actions of a specific covered establishment because the individual would not be present in the establishment where the standard items are prepared, and, thus, likely could not certify the actions the establishment takes to comply with the rule.

After considering these comments, we have revised the requirements for certification statements (*i.e.,* proposed § 101.11(c)(6)(i)(H), (c)(6)(ii)(D), (c)(6)(iii)(D), and (c)(6)(iv)(E), which we have renumbered in the final rule as described in the following sentences) to distinguish certifications that must be signed and dated by a responsible individual employed at the covered establishment from certifications that may be signed and dated by a responsible individual employed at either the covered establishment or at its corporate headquarters or parent entity. First, § 101.11(c)(3)(i)(F), (c)(3)(iii)(D), and (c)(6)(iv)(D) of the final rule require a statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate. We are using the term ''parent entity'' in addition to ''corporate headquarters'' because some business entities may not be ''corporations.''

Second, § 101.11(c)(3)(i)(G), (c)(3)(ii)(D), (c)(3)(iii)(E), and (c)(6)(iv)(E) of the final rule require a statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.,* types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

We are requiring that all certification statements be dated as well as signed. A date is standard practice on such documents and would be necessary, for example, to establish whether a certification signed in advance by a responsible individual at the parent entity can address nutrient analyses conducted over time.

(Comment 140) One comment opposed the proposed requirement that a covered establishment turn over its recipes to a governmental agency, because a covered establishment cannot be assured that its proprietary information will be protected and will not make it into the hands of competitors or unscrupulous governmental employees looking to sell or pass on trade secrets.

(Response 140) While we understand that some establishments may have concerns about the confidentiality of information inspected by FDA under § 101.11, we emphasize that we protect confidential information from disclosure, consistent with applicable statutes and regulations. Our disclosure of information is subject to the Freedom of Information Act (FOIA) (5 U.S.C. 552), the Trade Secrets Act (18 U.S.C. 1905), the FD&C Act, and our implementing disclosure regulations under part 20 (21 CFR part 20), which include protection for confidential commercial or financial information and trade secrets. To the extent that the comment is asserting that we have no procedures in place to protect the confidentiality of proprietary information, we disagree. We receive trade secret or confidential information on a regular and recurring basis. As noted previously, trade secrets and commercial or financial information that are privileged or confidential are protected from disclosure under the FOIA, the Trade Secrets Act, the FD&C Act, and our implementing disclosure regulations (see, *e.g.,* 21 U.S.C. 331(j), 18 U.S.C. 1905; 21 CFR 20.61(c)). Our disclosure regulations set forth specific procedures for assuring such protection (see part 20). A covered establishment that provides substantiation documentation to us may identify any information in such documentation that the establishment considers to be trade secret or confidential commercial or financial information (21 CFR 20.61(d)). Information so marked will not be disclosed to the extent such information is protected under the FOIA and our disclosure regulations (part 20).

(Comment 141) A few comments asserted that the proposed requirement that a responsible individual of the covered establishment certify that the recipe used for the standard menu item is identical to that used for the nutrient analysis is unreasonable and beyond the scope of the law. The comments considered that Congress directed us (in section 403(q)(5)(H)(x)(II)(aa) of the FD&C Act) to consider standardization of recipes, reasonable variation in serving size and formulation of menu items, inadvertent human error, training of food service workers, variations in ingredients, and other factors. One comment noted that this certification is not required by statute, and considered that it is not clear what regulatory purpose it would serve. The comments asserted that it is unreasonable to expect a covered establishment to prepare a standard menu item in a manner that is identical to the recipe on each given day. A few comments opposed asking employees to attest that they have followed recipes exactly and considered such a requirement to be unfair to employees because there are several factors that affect the recipe such as seasonal variations, market availability of certain ingredients, and modifying recipes to accommodate regional taste preferences. One comment suggested deleting the following proposed requirements in § 101.11(c)(6):

- For nutrient databases
  - The recipe posted on the database must be identical to that used by the restaurant or similar retail food establishment to prepare the menu item.
  - For the specified amounts of each ingredient identified in the recipe, a detailed listing (*e.g.,* printout) of the amount of each nutrient that that ingredient contributes to the menu item.
  - If this information is not available because the nutrition information was derived from a computer program, which is designed to provide only a final list of nutrient values for the recipe, a certificate of validation attesting to the accuracy of the computer program.
  - A statement signed by a responsible individual employed by the covered establishment that can certify that the information contained in the nutrient analysis is complete and accurate and that the recipe used to prepare the menu item is identical to that used for the nutrient analysis.
- For published cookbooks that contain nutritional information for recipes in the cookbook:
  - A copy of the recipe used to prepare the menu item and a copy of the nutrition information for that menu item as provided by the cookbook.
  - A statement signed by a responsible individual employed by the covered establishment certifying that the recipe used to prepare the menu item by the restaurant or similar retail food establishment is the same recipe provided in the cookbook. (Recipes may be divided as necessary to accommodate differences in the portion size derived from the recipe and that are served as the menu item but no changes may be made to the proportion of ingredients used.)
- For analyses:
  - A statement signed by a responsible individual employed by the covered establishment that can certify that the information contained in the nutrient analysis is complete and accurate and an additional signed statement certifying that the recipe used to prepare the menu item is identical to that used for the nutrient analysis.
- For nutrition information provided by other reasonable means:
  - The word ''detailed'' from the provision in § 101.11(c)(6)(iv)(A).
  - Documentation of the validity of that method.
  - A statement signed by a responsible individual employed by the covered establishment that can certify that the

information contained in the nutrient analysis is complete and accurate and that the recipe used to prepare the menu item is identical to that used for the nutrient analysis.

(Response 141) As discussed in Response 136, we are replacing each requirement (in proposed §§ 101.11(c)(6)(i)(H), (c)(6)(ii)(D), (c)(6)(iii)(D), and (c)(6)(iv)(E)) that a responsible individual of the covered establishment certify that the recipe used for the standard menu item is identical to that used for the nutrient analysis used to prepare the standard menu item with a requirement for a statement signed and dated by a responsible individual employed at the covered establishment certifying that the establishment has taken reasonable steps to ensure that the method of preparation (*e.g.,* types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined. Therefore, § 101.11(c) will not require a responsible individual of the covered establishment to certify that the recipe used for the standard menu item is identical to that used for the nutrient analysis used to prepare the standard menu item; nor will it require that a covered establishment prepare a standard menu item using a recipe that is identical to that used in a database (as proposed in § 101.11(c)(6)(i)(B)). Nevertheless, a covered establishment must ensure that its nutrition labeling is truthful and not misleading and that it has a reasonable basis for its nutrient content disclosures, as further discussed in Response 136.

As requested in Comment 136 and discussed in Response 136, we have revised the rule to require (in § 101.11(c)(2)) that the covered establishment take reasonable steps to ensure that the method of preparation (*e.g.,* types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined. As discussed in Response 135, we have revised proposed § 101.11(c)(6)(iv)(A) (which is renumbered as § 101.11(c)(3)(iv)(A) in the final rule), which addresses the information that must be provided to FDA, within a reasonable period of time upon request, when ''other reasonable means are used to provide the nutrition information.'' To emphasize that ''other reasonable means'' does not require analytical testing, § 101.11(c)(3)(iv)(A)) requires a detailed description of the ''means'' (rather than the ''method'') used to determine the nutrition information.

We also have removed proposed § 101.11(c)(6)(iv)(B), which would have required documentation of the validity of the method for ''nutrition information provided by other reasonable means.'' As evidenced by the examples we now provide of ''other reasonable means'' in § 101.11(c)(1), ''documentation of validity of that method'' generally would not apply to ''other reasonable means'' that are reasonably foreseeable.

Other than by removing proposed § 101.11(c)(6)(iv)(B) and the proposed provisions requiring that the recipe used to prepare a standard menu item be identical to the recipe used to determine the nutrition information for the standard menu item described previously, we are not deleting the remaining specific proposed provisions that one comment recommended deleting. The comment provided no explanation or basis for deleting those specific provisions. Further, these provisions establish requirements for substantiating determination of nutrient content for standard menu items provided by covered establishments. As we discussed in the proposed rule (76 FR 19192 at 19219), to determine whether a covered establishment has a reasonable basis for its nutrient content disclosures, as required by section 403(q)(5)(H) of the FD&C Act, and whether a standard menu item is otherwise misbranded under section 403(a)(1) of the FD&C Act, we must have access to the information substantiating the covered establishment's determination of nutrient content. Without these requirements, which provide access to substantiation documentation, we would not be able to efficiently determine whether a covered establishment's nutrition labeling is truthful and not misleading. Further, without access to substantiation documentation of the basis of a covered establishment's nutrient content disclosures, including recipe and ingredient information, we would not be able to determine whether an establishment has a reasonable basis for its nutrition content disclosures, as required by section 403(q)(5)(H)(iv) of the FD&C Act. Accordingly, such requirements are necessary for the efficient enforcement of the FD&C Act.

XX. Comments and FDA Response on Proposed Section 101.11(d)—Voluntary Registration To Elect To Be Subject to the Rule

Proposed § 101.11(d)(1) would provide that a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items could voluntarily register to provide the nutrition information required by § 101.11(b), and that in doing so they would no longer be subject to non-identical State or local nutrition labeling requirements. Proposed § 101.11(d)(2) would provide that the authorized official of a restaurant or similar retail food establishment as defined, may register with FDA. Proposed § 101.11(d)(3) would list the types of information (in brief, the contact information of each restaurant or similar retail food establishment, as well as contact information of an official onsite, trade names the restaurant or similar retail food establishment uses, preferred mailing address, and certification) that a restaurant or similar retail food establishment would need to provide to us in order to register voluntarily. Proposed § 101.11(d)(3) and (d)(4) would also describe the mechanism for submission by email, fax, mail, or online form. Finally, proposed § 101.11(d)(5) would require re-registration every other year within 60 days prior to the expiration of the current registration with FDA, and would provide that registration will automatically expire if not renewed.

In the following paragraphs, we discuss comments on these proposed provisions. We are finalizing them with the following changes for clarity.

- We are amending the titles of § 101.11(d)(4) and (d)(5) by replacing the question mark in each title with a period because these titles are not questions.
- We are deleting the revision date of Form FDA 3757 (*i.e.,* 7/10) from § 101.11(d)(3). The FDA form number is sufficient to identify the form. Moreover, the revision date may change as a result of the renewal of the form every 3 years under the Paperwork Reduction Act.
- We are moving proposed § 101.11(d)(3)(vi) and (d)(3)(vii) to be subparagraphs of § 101.11(d)(4) rather than § 101.11(d)(3) and redesignating them as § 101.11(d)(4)(i) and (d)(4)(ii), respectively. These provisions are directed to ''How to register'' rather than to ''What information is required?''
- For clarity, we are adding the form number (*i.e.,* Form FDA 3757) to the second sentence of § 101.11(d)(4).
- For completeness, we have added ''.gov'' to the end of the email address provided for voluntary registration under § 101.11(d)(4)(i). The complete email address now reads ''*menulawregistration@fda.hhs.gov*.''
- We have revised the format of the cross-reference, within § 101.11(d)(4) to § 101.11(d)(3) to read ''paragraph (d)(3)

of this section'' rather than ''§ 101.11(d)(3).'' We note that the proposed rule had identified the cross-reference as ''§ 101.11(c)(3).'' We revised this to ''§ 101.11(d)(3)'' in the correction document, but did not revise the format at that time.

(Comment 142) One comment supported the proposed registration requirements. One comment recommended that retail food establishments not covered by section 403(q)(5)(H) of the FD&C Act, regardless of whether they have fewer than 20 locations or if the sale of food is not the primary business activity, be allowed to elect to become subject to the requirements of section 403(q)(5)(H) of the FD&C Act by registering biannually with us. One comment referred to our discussions in the proposed rule that establishments such as cafeterias in schools and hospitals would not be covered by the rule under the proposed definition of ''restaurant or similar retail food establishment'' (see Footnote 1 at 76 FR 19192 at 19197 and discussion at 19230). This comment asked us to clarify whether there are some establishments (*e.g.,* hospitals or school cafeterias) that are not restaurants or similar retail food establishments and therefore cannot voluntarily register to be subject to the Federal menu labeling requirements. The comment also asked us to clarify whether certain food service contractor facilities can voluntarily register even if other facilities in the overall set of operations do not. The comment recommended that we allow a restaurant or similar retail food establishment to voluntarily register on an establishment-by-establishment basis and not require the chain or company to make a single corporate-wide determination. The comment asked us to allow a food service contract business to register some of their establishments in order to make well-informed decisions on whether to register the other establishments and modify their establishments and contracts accordingly (''rolling adoption''). The comment also asked if there were requirements for opting out of the Federal requirements after voluntarily registering. The comment asked whether a restaurant or similar retail food establishment is required to be covered by the menu labeling requirements for a specific length of time, once it has voluntarily registered.

(Response 142) The final rule defines ''restaurant or similar retail food establishment'' to mean a retail establishment that offers for sale restaurant-type food, except if it is a school as defined in 7 CFR 210.2 or 220.2. Under § 101.11(d), a restaurant or similar retail food establishment, as defined in § 101.11(a), that is not part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items (and, thus, is not subject to the requirements of section 403(q)(5)(H) of the FD&C Act) may voluntarily register to be subject to the requirements established in this rule. It does not matter whether the sale of food is the establishment's primary business activity, because the definition of restaurant or similar retail food establishment in this rule does not include a primary business test. Many establishments that would not have been a ''restaurant or similar retail food establishment'' under the definition we proposed (including establishments in hospitals) would be a restaurant or similar retail food establishment under the definition established in this rule (see the discussion of the definition of restaurant or similar retail food establishment in section VI.B). Whether any such establishment is automatically covered by the rule generally would depend on whether the establishment satisfies all other criteria in the definition of ''covered establishment'' (*i.e.,* part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, *e.g.,* individual franchises) and offering for sale substantially the same menu items).

Section 403(q)(5)(H)(ix) of the FD&C Act provides that an authorized official of any restaurant or similar retail food establishment not subject to the requirements of section 403(q)(5)(H) may elect to become subject to the requirements by registering with FDA. Accordingly, any establishment that meets the definition for a restaurant or similar retail food establishment, as provided in § 101.11(a), that is not already subject to the requirements of section 403(q)(5)(H) of the FD&C Act can voluntarily register to become subject to the requirements under § 101.11(d). Establishments that do not meet the definition of ''restaurant or similar retail food establishment'' (*e.g.,* drug stores that do not offer for sale any restaurant-type food) cannot voluntarily register.

Under § 101.11(d), an authorized official is permitted to register an individual restaurant or similar retail food establishment on an establishment-by-establishment basis, in that the authorized official may register a single restaurant or similar retail food establishment or multiple restaurants or similar retail food establishments within a chain on a single registration form, provided that the individual is authorized to do so for all of the restaurants or similar retail food establishments included on the form (Form FDA 3757) submitted. Whether a decision to register is made on an establishment-by-establishment basis or is a corporate-wide decision applying to many or all establishments within a chain is a matter for the restaurant or similar retail establishments and any corporate management to determine. This is as true for restaurants or similar retail food establishments operated by contractors as it is for other restaurants or similar retail food establishments.

The rule does not establish a date by which a restaurant or similar retail food establishment must register in order to ''opt in'' as a covered establishment and, thus, establishments within a chain could approach the voluntary registration using the ''rolling adoption'' requested by one comment.

A restaurant or similar retail food establishment that has voluntarily registered under § 101.11 must comply with the requirements of sections 403(a)(1), 403(f), and 403(q)(5)(H) of the FD&C Act and § 101.11 for 2 years after the date of registration and may not ''opt out'' until the 2 years has passed. If the restaurant or similar retail food establishment wants to ''opt out,'' the mechanism to do so would be to let the registration lapse (*i.e.,* not re-register) after the 2 years have passed.

XXI. Comments and FDA Response on Proposed § 101.11(e)—Signatures

Proposed § 101.11(e) would provide that signatures obtained under the voluntary registration provisions that meet the definition of electronic signatures in § 11.3(b)(7) would be exempt from the requirements of part 11 of the CFR (requirements for electronic records and signatures).

We received no comments on this proposed provision and are finalizing it without change.

XXII. Comments and FDA Response on Proposed § 101.11(f)—Misbranding

Proposed § 101.11(f) would provide that ''a standard menu item offered for sale in a covered establishment'' would be ''deemed misbranded under sections 201(n), 403(a), and/or 403(q) of the Federal Food, Drug, and Cosmetic Act if its label or labeling is not in conformity'' with the requirements for nutrition labeling and determination of nutrient content at § 101.11(b) and (c).

While we received no comments on this proposed provision, we are finalizing this provision with one change. We are including a reference to section 403(f) of the FD&C Act to clarify

that failure to comply with the requirements of § 101.11(b) could cause a food to be misbranded under section 403(f) of the FD&C Act. Section 403(f) of the FD&C Act provides that a food shall be deemed misbranded ''if any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.'' For example, as discussed in Response 127, if a calorie declaration for a standard menu item that is a self-service food or food on display is not declared in a manner that complies with § 101.11(b)(2)(iii)(A)(*3*)(*ii*), in that the declaration is not clear and conspicuous, the standard menu item would be misbranded under section 403(f) of the FD&C Act in addition to section 403(q) of the FD&C Act.

XXIII. Comments and FDA Response on Effective Date

A. Proposed Effective Date and Request for Comment

The proposed rule specified that the final rule would become effective 6 months from the date of its publication in the **Federal Register** (76 FR 19192 at 19219). We noted that compliance is expected to yield significant public health benefits because consumers will have calorie and other nutrition information when they make menu choices. Because of this benefit, we stated that it is reasonable to make the requirements effective as soon as practicable. We recognized, however, the potential difficulties of implementing the rule in this timeframe, and requested comment on whether the effective date should be extended for a greater period of time after the publication of the final rule. In particular, we requested comment on whether a 9-month or 1-year implementation timeframe would be more appropriate.

We also requested comment, supported by data, concerning how much time is needed for covered establishments to come into compliance with the rule, including, if possible, data on whether specific provisions of the rule can be more quickly implemented than others. We also requested comment on whether we should provide for staggered implementation based on the size of a chain or of a specific franchisee and again requested that suggestions be supported by data.

B. Comments on Proposed Effective Date

(Comment 143) Many comments supported our proposed 6-month effective date. Some comments noted that State and local jurisdictions with menu labeling requirements implemented and enforced the requirements in 6 or 7 months. One comment stated that many large chains have already conducted nutrient analyses for their menu items. In contrast, another comment reported the implementation time frames for 12 State and local requirements. This comment noted that restaurants subject to State or local menu labeling requirements have had no less than 6 months to comply with such requirements. This comment reported that one city (Philadelphia) provided more than 1 year for compliance and one State (Oregon) provided 6 months for implementation of Phase 1 of its requirements, and an additional year for compliance with Phase 2 of its requirements. This comment urged us to allow establishments at least 1 year to come into compliance with the Federal requirements.

Several comments opposed the 6-month effective date and requested an effective date of at least 1 year. Some comment noted that an effective date of at least 1 year would be necessary for covered establishments to develop and install redesigned menus. In particular, one comment from national associations representing a number of restaurants estimated that there are 250,000 to 275,000 covered restaurants in the United States, not including similar retail food establishments that would be covered under the rule. This comment recommended that we adopt an implementation period of not less than 1 year after the publication of the final rule and noted that extending the time period to 1 year would allow most restaurants to incorporate adding calorie declarations to menus and associated menu redesigns with regular menu replacement cycles, thereby reducing costs. This comment identified several specific steps necessary for covered establishments to comply with the rule, including:

- ''Digest the final rule,'' including determining what are menus and menu boards, what are standard menu items, what are custom orders, and what are temporary menu items or otherwise excluded foods;
- Determine nutrient content levels and ensure that their bases for determining such nutrient information are sound;
- Prepare and print written nutrition information;
- Redesign menus and menu boards to include calories;
- Roll out new menus and menu boards simultaneously to chain restaurants nationwide;
- Update food preparation procedures to ensure consistency and ensure that reasonable steps are in place to ensure standard menu items are prepared consistently;
- Create processes where information related to standard menu items, *e.g.,* ingredients supplier data, is periodically updated; and
- Develop and conduct training.

This comment also presented the following estimated time frames to conduct some of these steps:

- Four weeks to digest the requirements of the rule;
- Twenty-four weeks to design new layouts, obtain reviews and approvals, and for production and kitting; and
- Eight weeks for shipping.

Other comments that supported a 1-year effective date presented similar reasons, noting that a 1 year effective date would allow restaurants to properly review the final rule, analyze covered food items, and incorporate nutrition labeling into their truck stop and travel plaza restaurants. Some comments expressed concern that demand for menu item nutrient analysis and redesigning menu boards will skyrocket upon publication of the final rule, thereby overwhelming testing laboratories and companies that design menus and menu boards.

(Response 143) We agree that covered establishments will need more than 6 months to come into compliance with the rule, including making changes to menus and menus boards. While some establishments already are subject to State or local nutrition labeling requirements for foods sold in such establishments, others are not. Moreover, even those establishments that already are subject to State or local requirements nutrition labeling requirements may not be required to disclose such nutrition information in the format and manner specified in section 403(q)(5)(H) of the FD&C Act and this rule. We carefully considered the activities and associated time frames identified by the comments, including the comment from national organizations representing restaurants, and we agree that the rule should provide for an effective date of 1 year to comply with the Federal requirements. Most comments, even the comment noting that one State and one local

government provided more than 1 year for full implementation, requested an effective date of ''at least 1 year.''

We also agree that a time frame that enables establishments to make changes to menus and menu boards during a time period that coincides with their regular menu replacement cycles would save time and resources. In addition, we acknowledge that companies that design and produce menu boards will receive many orders to update menu boards to comply with the rule. We note that a covered establishment that experiences difficulty obtaining new menus or menu boards as a result of increased demand as the effective date draws near will have other ways to comply with the rule without replacing the menus or menu boards. For example, we would not object if a covered establishment declares calorie information by applying stickers or pieces of paper to menus or menu boards. For packaged foods, we have taken the position for some time that the Nutrition Facts label may be printed on a sticker and affixed to a package, as long as the sticker adheres to the product under the intended storage conditions (Ref. 38; see L16). We also have long taken the position that stickers may be used to make changes in labeling such as correcting label mistakes provided that the final label is correct and complies with all regulations at the time of retail sale, the stickers do not cover other mandatory labeling, and the stickers adhere tightly (Ref. 38, see L55).

Likewise, we acknowledge that there could be some increased demand for nutrient analysis by testing laboratories as the effective date draws near. Importantly, the rule does not require analytical testing of standard menu items; analytical testing is merely one option available to a covered establishment to determine nutrient values. Other options include use of nutrient databases, cookbooks, or other reasonable means, including the use of Nutrition Facts on labels on packaged foods that comply with the nutrition labeling requirements of section 403(q)(1) of the FD&C Act and § 101.9, FDA nutrient values for raw fruits and vegetables in Appendix C of part 101, or FDA nutrient values for cooked fish in Appendix D (see § 101.11(c)(1)). In addition, as noted by the comments, many establishments that are part of large chains have already determined nutrient values for their menu items. As discussed in Response 138 and Response 139, this rule provides that corporate headquarters or a parent entity, rather than each individual covered establishment, may determine and certify nutrient values, as requested by comments. Thus, to the extent establishments' corporate headquarters or parent entity have determined nutrient values for standard menu items offered for sale in such establishments, individual covered establishments can come into compliance with this rule without significantly overwhelming testing laboratories, even if such establishments choose analytical testing as the means to determine nutrient values.

For all of these reasons, and as discussed in more detail in section XXIII.C, we have established an effective date for this rule that is 1 year from the date of publication of this document. Thus, the final rule is effective on December 1, 2015.

(Comment 144) One comment that recommended a minimum of 12 to 18 months for establishments to comply with the rule provided information about its experience from a 2010 rollout of new menu boards for all its domestic stores. This comment identified the following steps and corresponding time frames for this 2010 rollout:

- 2 months to develop new menu board templates for the seven types of menu boards for its various types of store locations (mall stores, mall kiosks, mall carts, stadium stores, stadium carts, etc.);
- 8 months to develop, program, and test an ordering site to accommodate more than 850 individual store menus;
- 2 months to receive the orders and lay out all custom menu boards; and
- 2 months to produce and ship new menu boards to its stores.

(Response 144) We appreciate that this comment provided its specific experience from a company-wide rollout of new menu boards. The steps identified by this comment are similar to the steps identified by the comment from national associations representing restaurants, although with longer timeframes. However, as discussed in Comment 143 these national associations also noted that extending the time period to 1 year would allow most restaurants to incorporate adding calorie declarations to menus and associated menu redesigns with regular menu replacement cycles. We therefore disagree that the time frames experienced by one entity during a company-initiated rollout of new menu boards should determine the time frame for compliance by all covered establishments.

(Comment 145) Some comments requested an effective date of more than 12 months. One comment requested an 18-month effective date because it considered that many requirements are still unclear. Another comment requested an 18-month to 2-year effective date for similar retail food establishments, even if there is a shorter time for restaurants. According to this comment, establishments need time to comply properly with the requirements and rushing through compliance could result in mistakes that may be confusing to consumers and would require additional industry resources to correct.

A few comments requested a 2-year effective date. One comment asserted that there will be a steep learning curve and time is needed to train employees and develop and print display materials. A few comments maintained that a 2-year compliance period is appropriate because, according to one comment, we used a 2-year uniform compliance period when implementing the NLEA. According to another comment, a 2-year timeframe is reasonable as long as nutrition information is available in brochures and online.

(Response 145) We disagree that an effective date over 1 year (such as 18 months or 2 years, as suggested by the comments) is necessary. Many comments seeking a longer effective date focused on the need to train employees. Such training does not need to wait until all implementation activities are complete—*e.g.,* such training can begin while an establishment is waiting for delivery of its revised menus and menu boards.

We also disagree with the comment asserting that similar retail food establishments need more time than restaurants to comply with the rule. The comment provided no basis for why similar retail food establishments should be treated differently from restaurants or why such establishments would need more time for compliance than restaurants.

We discuss the applicability of the uniform compliance date in section XXIII.C.

(Comment 146) One comment asserted that there will be an unfair competitive advantage for larger companies because of the ability of larger companies to leverage their market position with the menu board producers. One comment requested a grace period to come into compliance if a covered establishment has adopted and followed a reasonable program to monitor changing nutrient values and update menus and menu boards at reasonable intervals coinciding with typical cycles.

(Response 146) In the proposed rule, we specifically requested that comments about whether we should provide for staggered implementation based on the size of a chain or of a specific franchisee be supported by data. The comment

asserting that there will be an unfair competitive advantage for larger companies (because of their ability to leverage their market position with the menu board producers) provided no data for its assertion; therefore we have no information that could assist us in considering whether or how much additional time might be appropriate. Further, as discussed in Response 143, covered establishments can use a number of ways to comply with this rule without replacing menus or menu boards; for example, they can apply stickers or pieces of paper to menus or menu boards. For these reasons, we do not believe there is a sufficient basis to establish a staggered implementation period based on the size of the chain or of a specific franchise.

Nevertheless, we can work with establishments that are not in compliance by the effective date of this rule on a case-by-case basis, taking into consideration a number of factors, including specific steps an establishment has taken towards compliance.

(Comment 147) One comment requested that we allow 1 year for implementation, rather than 6 months, to provide covered establishments with adequate time to come into compliance given contractual requirements. For example, the comment said that it maintains a database with over 35,000 recipes which, in turn, may be modified or adapted by the specific restaurant or similar retail food establishment for local needs and tastes, limitations of the establishment, contractual specifications, and other restrictions (*e.g.,* an establishment's determinations as to types of offerings). In addition, the comment stated that contractors rely on suppliers to provide nutritional information and, therefore, we should allow adequate time to retrieve data from these sources.

(Response 147) As discussed in section XXIII.C, we are establishing an effective date of 1 year from the date of publication of this rule. We note that the comment refers to recipes that may be modified or adapted by a specific restaurant or similar retail food establishment. In section VI.F, we discuss how such modifications can affect whether an establishment is offering for sale substantially the same menu items (and, thus, satisfies this criterion in the definition of covered establishment).

C. Effective Date and Compliance Date for This Rule

We are establishing the effective date to be 1 year from the date of publication of this document, *i.e.,* the final rule is effective on December 1, 2015, (see **DATES**). We believe that extending the effective date from 6 months to 1 year provides sufficient time for covered establishments to come into compliance with the requirements without a significant negative impact on public health.

We expect covered establishments to come into compliance with the requirements of this rule by December 1, 2015, *i.e.,* the same date as the effective date of this rule. Although we are issuing this final rule after January 1, 2013, there is sufficient justification for establishing a compliance date of December 1, 2015, to enforce the provisions of this final rule, rather than January 1, 2016, which FDA has established as the next uniform compliance date for other food labeling changes required by food labeling regulations that are issued between January 1, 2013, and December 31, 2014 (77 FR 70885; November 28, 2012). Typically, our uniform compliance dates for food labeling regulations focus on changes made to the requirements for labels of packaged foods and seek to minimize the economic impact of such label changes, in relevant part, by allowing manufacturers to come into compliance with such regulations by one particular compliance date rather than several different dates (*e.g.,* 77 FR 70885; 75 FR 78155 (December 15, 2010)). By providing one uniform compliance date, we enable manufacturers to avoid multiple short-term label revisions that would otherwise occur if not for the uniform compliance date. However, this rule does not establish requirements for the labels of packaged foods, and therefore would not cause food label revisions comparable to other food labeling regulations typically addressed by our uniform compliance dates. In addition, standard menu items offered for sale in covered establishments were not subject to Federal nutrition labeling requirements before the enactment of section 4205 of the ACA. As a result, unlike packaged foods, standard menu items currently are not subject to several different Federal food labeling regulations that may provide for different compliance dates. Further, a comment from national associations representing restaurants reported that extending the time period from the 6 months that we proposed, to 1 year, would allow most restaurants to comply with the rule as part of regular menu replacement cycles, thereby lessening costs. For these reasons, along with the reasons discussed previously, we believe that 1 year is sufficient time for covered establishments to come into compliance with the requirements of this rule. Waiting until FDA's next uniform compliance date of January 1, 2016, would create unnecessary delay in the enforcement of this rule and could minimize public health benefits.

XXIV. Comments and FDA Response on Compliance

In the proposed rule, we noted that some provisions of section 4205 of the ACA became requirements immediately upon enactment of the law and that we intended to exercise enforcement discretion until after we had completed notice and comment rulemaking. We encouraged our State and local partners to proceed in a similar way. We requested comment on how we should implement the rule, including whether specific provisions of the rule can be more quickly implemented than others (76 FR 19192 at 19220).

(Comment 148) One comment asked us to develop a protocol for checking the accuracy of the nutritional information provided by covered establishments. One comment recommended that we undertake random testing as resources allow. Another comment recommended that testing be done annually and kept on a public file to ensure that the portions continue to be within 5 percent tolerance of the original nutritional information. The comment suggested that if deviations are found, the company would either retest in 30 days or pay a penalty fee that would be passed to a childhood obesity campaign.

(Response 148) The rule provides several options for how covered establishments can determine nutrition information. While analytical testing of standard menu items may be appropriate in some cases (*e.g.,* when the reasonable basis that a covered establishment uses to determine nutrient values is analytical testing), we expect our routine approach to evaluating the accuracy of the nutrition information to be based on the particular facts at issue, including the reasonable basis used by the covered establishment, which may be means other than analytical testing. Consistent with our approach to inspection of food processing facilities, we do not expect to establish a public file with the results of any testing we conduct. Under the Freedom of Information Act and our regulations in part 20, a person who wishes to see the results of our inspections may submit a request to do so.

Regarding the comment suggesting that we develop a protocol for checking the accuracy of the nutritional

information provided by covered establishments, we decline to include such a protocol for checking the accuracy of the nutritional information in the rule at this time. Section 101.11(c) includes requirements for determining nutrient content and section XVII further discusses such requirements, including the requirement that nutrient declarations be accurate and consistent with the specific basis used to determine nutrient values. After we have had experience in evaluating compliance with the rule, we will consider whether to develop such a protocol.

(Comment 149) A few comments asked us to clarify our enforcement strategy and quickly establish an enforcement protocol. One comment stated that the proposed rule is virtually silent on how the menu labeling requirements will be enforced and encouraged us to permit the industry to comment on our enforcement strategy before it is included in the rule. One comment recommended that we issue guidance documents to the industry to better clarify matters of uncertainty that will persist following issuance of the rule.

One comment asked us to provide details on the penalties for noncompliance. Another comment recommended that we issue warning letters prior to instituting civil penalties against a covered establishment, particularly if the proposed rule's ambiguities are not clarified in the final rule. The comment maintained that a covered establishment may have made a good faith effort to comply and that warning letters will encourage compliance and inform establishments how they have fallen short of compliance. The comment recommended that we use a tiered penalty structure, whereby minor violations (*e.g.,* inadequate font size of nutrition information) are treated less harshly than more serious violations (*e.g.,* a clear lack of effort to place calorie information on printed menus). The comment also encouraged us to have a progressive penalty system for violations, whereby first violations are treated less harshly (*e.g.,* a warning letter) than repeated violations. The comment maintained that this is especially crucial in the first few years the rules are being implemented as covered establishments familiarize themselves with the new requirements.

(Response 149) We are establishing these regulations under sections 201(n), 403(a)(1), 403(f), and 403(q)(5)(H) of the FD&C Act, as well as under section 701(a) of the FD&C Act. As discussed in the proposed rule and in section XXII, failure to comply with the rule will render the food misbranded under section(s) 201(n), 403(a), 403(f), or 403(q) of the FD&C Act (76 FR 19192 at 19219). Penalties are already set forth in the FD&C Act, and violations of § 101.11 may result in enforcement action consistent with those penalties. For example, introducing, delivering for introduction, or receiving a misbranded food in interstate commerce, or misbranding a food while it is in interstate commerce or being held for sale after shipment in interstate commerce, are prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331), carrying criminal penalties under section 303 of the FD&C Act (21 U.S.C. 333). In addition, under section 302 of the FD&C Act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited action. Under section 304(a)(1) of the FD&C Act (21 U.S.C. 334(a)(1)), a food that is misbranded when introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce may be seized by order of a Federal court. We expect to issue guidance to help covered establishments with compliance.

The tiered enforcement approach described by the comment is similar to the approach we currently take for other misbranded food, and we generally expect our enforcement approach to misbranding violations of this rule to be similar to that for other misbranded food. Nevertheless, enforcement will be considered on a case-by-case basis depending on the specific facts and circumstances.

(Comment 150) One comment asked us to focus our enforcement actions on helping with compliance, rather than seeking monetary penalties, at least until establishments have an opportunity to fully adopt the requirements. This comment maintained that flexibility is needed in the initial phases of implementation for facilities that operate under Federal Government contracts so that they can continue to comply with requirements mandated by specific Government Agencies. As a result, the comment recommended that we provide flexibility for contract food providers that provide services to Government facilities under a specified program.

(Response 150) We recognize that covered establishments will need time to comply with the nutrition labeling requirements of this rule during the initial phase of implementation. To provide more time to do so, this rule is not becoming effective until 1 year after the date of publication of this document (see the discussion in section XXIII.C of this document).

A covered establishment has responsibility to comply with all requirements of the rule. We acknowledge that a covered establishment may need to update its business and contractual relationships with its suppliers in order to do so.

(Comment 151) One comment asked us to permit stores to register points of contact to which we will address enforcement because experience shows that involving ''corporate parents'' of individual franchises or the owner of multi-store chains is the most effective way to manage enforcement issues. The comment recommended that we notify these contacts in the event of an enforcement action. Similarly, the comment recommended that we designate specific contacts for informal guidance and advice and develop a menu labeling hotline telephone number or email address to which store operators can ask specific questions. The comment considered that doing so would increase compliance and ease the administrative burden on its members.

(Response 151) Each individual restaurant or similar retail food establishment is responsible for disclosing the required nutrition information for its standard menu items and otherwise complying with the requirements of sections 403(q)(5)(H), 403(a)(1), and 403(f) of the FD&C Act and § 101.11. Persons exercising authority and supervisory responsibility over such establishments may also be held liable for violations of the FD&C Act. See Response 3. Our decisions regarding enforcement actions will be determined on a case by case basis. In general, we intend to notify a ''corporate parent'' as appropriate (see *e.g.,* Refs. 39 and 40). Although § 101.11(d) provides for voluntary registration for restaurants and similar retail food establishments that are not subject to the nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act, and requires contact information, these requirements only apply to such establishments that would not be subject to the rule without registering.

We already maintain a telephone hotline where industry may contact us for questions about compliance with our regulations (1–888–SAFEFOOD (1–888–723–3366)). Staff who are assigned to the hotline will have or obtain the information to answer questions about this rule. In addition, a covered establishment may direct questions to the contact person identified in this document (see **FOR FURTHER INFORMATION CONTACT**), to the contact telephone number provided in any subsequent

guidance, and to a general email mailbox for industry questions (*industry@fda.gov*). A covered establishment also may send written inquiries to Center for Food Safety and Applied Nutrition (HFS–009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

(Comment 152) A few comments recommended that we preapprove menus and menu boards. One of these comments recommended that we do so even if a fee was required. The comment maintained that an approval process would alleviate covered establishments from having to pay the costs to replace menus that they thought met the menu labeling requirements.

(Response 152) We decline the request of these comments. Section 403(q)(5)(H) of the FD&C Act does not require that we preapprove menus and menu boards, nor do we have the resources to do so at this time. Section 403(q)(5)(H) of the FD&C Act and this rule set forth and specify the requirements for menus and menu boards such that a covered establishment should be able to determine whether its menu or menu board meets the applicable requirements. Further, a covered establishment may contact us with questions about compliance, as discussed previously in Response 151.

(Comment 153) One comment asked us to clarify that compliance is the responsibility of each establishment and that if someone fails to comply, only that standard menu item in the particular establishment is misbranded. The comment expressed concern that without clarity on this point, States and localities may cite franchisors for violations by franchisees, and plaintiffs' attorneys may sue franchisors for violations by franchisees under consumer protection laws.

(Response 153) With regard to what food is misbranded if there is a failure to comply with the regulations, this would be determined based on the particular facts of the situation (see also Response 3).

(Comment 154) Some comments asked us to allow flexibility for when a covered establishment must update menus to reflect changes in nutrient content. One of these comments asked us to clarify that any temporary inconsistencies resulting from periodic updating will not result in a violation of the law. The comment expressed concern that nutrient values may change because of ingredient changes, use of different suppliers, suppliers updating nutritional analysis with no changes in formulation, and reformulation of menu items based on consumer feedback. The comment asked us to state that values found not current will not raise a compliance issue if the covered establishment can demonstrate that it has adopted a reasonable program to monitor changing values and that it updates materials at reasonable intervals based on the manner and frequency in which it changes menus and other labeling. The comment also recommended that covered establishments be able to update their menus and menu boards at reasonable intervals coinciding with typical cycles to change menus and, at a maximum, values that require updating be updated at least once a year. One comment asked that the final rule clearly state that covered establishments are responsible for maintaining the accuracy of their nutrient declarations, including keeping this information up-to-date as their menus change.

(Response 154) Nutrition labeling for a standard menu item must be truthful and not misleading, consistent with the specific basis used to determine nutrient values, and otherwise in compliance with the requirements of sections 403(a)(1), 403(f), and 403(q)(5)(H) of the FD&C Act and § 101.11. We recognize that changes in nutrition information for standard menu items could cause a covered establishment to change a menu or menu board even if the list of menu items has not changed. In general, revised nutrition must be posted before serving the food. Compliance will be determined on a case-by-case basis depending on the specific facts and circumstances. We recommend that a covered establishment coordinate changes in menu items that are significant enough to affect nutrient content with the introduction of new items that also require updating a menu or menu board to help minimize costs. As discussed in Response 143, covered establishment may also use measures such as stickers to update nutrient content on menus or menu boards.

(Comment 155) Several comments requested clarification on who would enforce the rule. One comment asked that delegation of inspection authority to the States be explicit, and asserted that the provision in 21 U.S.C. 337 authorizing States to enforce Federal law has rarely been used. This comment stated that we could use 21 U.S.C 372(a)(1)(A) to provide technical assistance and funding to States and locals for enforcement. The comment suggested that we set up a simple process for local health inspectors to report violations to us, *e.g.,* a postcard to be filled in and sent to us with a tear off receipt to be left with the restaurant manager. The comment also suggested that we develop a system to collect and store reports of violations in a database. A few comments recommended that the final rule specify that enforcement procedures of States are not affected by section 4205 of the ACA.

One comment recommended that we work with headquarters of chain restaurants and similar retail food establishments to ensure compliance and then have our District Offices assess compliance in the States.

One comment stated that States and locals cannot be expected to enforce the Federal menu labeling requirements without significant funding. The comment stated that the enforcement process in its State is already overburdened and, therefore, the Federal Government should enforce the requirements. Other comments recommended that we rely on States and localities and provide training and funding. A few comments stated that historically restaurant inspections are done by the States and localities, and one comment recommended that we use the contractual regime of food safety inspections used with the enforcement of the NLEA. One comment stated that local restaurant inspectors can add the enforcement of menu labeling to their current inspections. One comment recommended that we enforce fines and penalties for noncompliance and direct any resulting funds to inspection programs enforcing the menu labeling requirements.

One comment stated that it is not always practical for States and locals to enforce section 4205 of the ACA as delegates of FDA; rather we should encourage and support enactment of identical requirements that fit into local and State food codes.

One comment suggested that the rule include specific provisions that would be binding on State and local jurisdictions relative to enforcing the rule. The comment stated that the right to a notice of a violation, the opportunity to cure a violation, and the opportunity to have a re-inspection before an adverse decision by the enforcing agent, *e.g.* a citation, vary enormously from jurisdiction to jurisdiction, at the State and at the local level. The comment suggested that we include specifics such as:

- The enforcement agency at initial inspection provides written notice of violations;
- The enforcement agency gives the establishment a period of time to cure the violations (*e.g.,* 15–30 days);
- The enforcement agency would re-inspect after cure period; and
- If violations are not cured, the enforcement agency would issue

adverse decision applying fine or other action that would apply under the enforcement agency's regulations or applicable State or local laws.

The comment stated that these actions would only apply to calorie labeling and not to other violations related to safety.

(Response 155) Collectively, these comments address three mechanisms by which States (and, in some cases, local jurisdictions) could have a role in enforcing the provisions of section 403(q)(5)(H) of the FD&C Act and this rule:

- In general, a State or political subdivision of a State may establish food nutrition labeling requirements that are identical to applicable Federal requirements, including the requirements of this rule. In this case, the State or local jurisdiction would act on its own behalf to enforce its own requirements, albeit requirements that are identical to the Federal requirements.
- Under 702(a)(1)(A) of the FD&C Act (21 U.S.C. 372(a)(1)(A)), FDA is authorized to conduct examinations and investigations for the purposes of the FD&C Act through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof (such as a locality), duly commissioned to act on behalf of FDA. In this case, the State or local representative would act on our behalf to enforce the Federal requirements.
- In general, under section 310(b) of the FD&C Act (21 U.S.C. 337(b)), a State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 403(q) of the FD&C Act, including the nutrition labeling requirements for standard menu items under section 403(q)(5)(H) of the FD&C Act, if the food that is the subject of the proceedings is located in the State provided that other requirements and conditions are met. In this case, the State acts on its own behalf to enforce the Federal requirements.

We have successfully partnered with States to conduct examinations and inspections in other contexts, including inspections of food processing facilities on our behalf (Ref. 41). We expect to continue to cooperatively leverage the resources of Federal, State, and local Government Agencies as we strive to obtain industry-wide compliance with this rule.

XXV. Final Regulatory Impact Analysis

FDA has examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a detailed Regulatory Impact Analysis (RIA) that presents the benefits and costs of this final rule (Ref. 42) which is available at *http://www.regulations.gov* (enter Docket No. FDA–2011–F–0172). The full economic impact analyses of FDA regulations are no longer (as of April 2012) published in the **Federal Register** but are submitted to the docket and are available at *http://www.regulations.gov.* We also post the full economic impact analyses of FDA regulations at the following Web site: *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

This rule is designated an ''economically'' significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule was reviewed by OMB. In particular, Executive Order 12866 directs each Agency engaged in rulemaking to ''identify the problem that it intends to address''—that is, the essential purpose of the rule. As a separate step in its rulemaking, Executive Order 12866 directs the Agency to ''assess both the costs and the benefits of the intended regulation . . . , recognizing that some costs and benefits are difficult to quantify.''

Executive Order 13563 confirms that ''each agency is directed to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. Where appropriate and permitted by law, each Agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify.'' Here, the essential purpose of the rule is to make nutrition information for certain foods available to consumers in a direct, accessible, and consistent manner to enable consumers to make informed and healthful dietary choices. The full analysis—contained in the RIA—of anticipated and quantifiable costs and benefits from the promulgation of the rule does not alter this fundamental purpose. Nor does it fully capture the unquantifiable benefits of greater consumer understanding regarding dietary choices and their impact on health.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. According to our analysis, we believe that the final rule will have a significant economic impact on a substantial number of small entities, and we have accordingly analyzed regulatory options that would minimize the economic impact of the rule on small entities consistent with statutory objectives. We have crafted the final rule to provide flexibility for compliance.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA has determined that this final rule has met the threshold under the Unfunded Mandates Reform Act.

The analyses that we have performed to examine the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995 are included in the RIA (Ref. 42).

We had prepared a ''Preliminary Regulatory Impact Analysis'' (Ref. 43) in connection with the proposed rule. We also included sections titled ''Summary of Preliminary Regulatory Impact Analysis'' and ''Initial Regulatory Flexibility Analysis'' in the preamble to the proposed rule (76 FR 19192 at 19220 through 19225). We received comments on our analysis of the impacts presented in those sections, and the RIA (Ref. 42) contains our responses to those comments.

XXVI. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given in this section of the document with estimates of the annual reporting, recordkeeping, and third-party disclosure burden. Included in each burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We had included a section titled ''Paperwork Reduction Act of 1995'' in the preamble to the proposed rule (76 FR 19192 at 19225 through 19229). We received one comment on our analysis of the burdens presented in that section.

(Comment 156) One comment stated that the recordkeeping burdens of the proposed rule would impose millions of dollars in cost per year. The comment stated that these burdens are needless.

(Response 156) We disagree that the burdens are needless. Providing accurate, clear, and consistent nutrition information, including the calorie content of foods, in restaurants and similar retail food establishments will make such nutrition information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices.

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Information Collection Provisions of the Final Rule on Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

A. Reporting Requirements

Description of Respondents: The likely respondents to this information collection are restaurants and similar retail food establishments that voluntarily elect to be subject to the Federal requirements of this rule by registering with FDA. These establishments include chain retail food establishments and eating and drinking places such as full- and limited-service restaurants, snack bars (including, for example, ice cream, donut, and bagel shops and similar establishments), cafeterias and drinking places, managed food service facilities, grocery stores, supermarkets, convenience stores, general merchandise stores, lodging facilities, recreational venues, sports venues, performing arts venues, and movie theaters.

Description: Restaurants and similar retail food establishments not subject to the ACA's requirements may voluntarily elect to be subject to the Federal requirements by registering with FDA. Authorized officials for restaurants and similar retail food establishments must provide FDA with the following information on Form FDA 3757: Their contact information including name, address, phone number, and email address for their authorized official; the contact information including name, address, phone number, and email address for each restaurant or similar retail food establishment being registered, as well as the name and contact information for an official onsite, such as the owner or manager, for each specific restaurant or similar retail food establishment; all trade names the restaurant or similar retail food establishment uses; preferred mailing address, if different from location address for each establishment; and certification that the information submitted is true and accurate, that the person submitting it is authorized to do so, and that each registered restaurant or similar retail food establishment will be subject to the requirements of section 403(q)(5)(H) of the FD&C Act and § 101.11 of the final rule.

To keep the establishment's registration active, the authorized official of the restaurant or similar retail food establishment must register every other year within 60 days prior to the expiration of the establishment's current registration with FDA. Registration will automatically expire if not renewed.

TABLE 1—ESTIMATED REPORTING BURDEN [1]

21 CFR part 101	Number of respondents	Number of responses per respondent per year	Total annual responses	Average burden per response (in hours)	Total hours
Initial Burden (annualized over 3 years):					
§ 101.11(d) Initial Registration	3,559	1	3,559	2	7,118
Annual Burden:					
§ 101.11(d) Registration Renewal	5,340	1	5,340	0.5 (30 minutes)	2,670
Total Burden Hours					9,788

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We lack data on the number of restaurants and similar retail food establishments that might voluntarily register to comply with this final rule. We do not expect the net benefit for voluntary registration for many non-covered establishments to be positive and in the RIA (Ref. 42) we indicate that as of the conducting of this analysis, no establishments have voluntarily registered with FDA. Therefore we did not estimate a significant burden in the RIA. However, in the event that a few register anyway, or find positive incentive to do so, for the purposes of this PRA analysis, we estimate the burden such establishments will face. We believe that implementation of the final rule, and the resulting attention to the nutrition content of standard menu items, may give non-covered establishments an incentive to voluntarily disclose calorie and other nutrition information. We believe that the only types of establishments that would likely face a positive incentive to voluntarily register are some restaurants and some grocery, convenience, and general merchandise stores that do not already provide this information in some form or another at the point of purchase. We estimate that 5 percent of these establishments may register, or 10,678 [(5% volunteer × 47% no nutrition info × 348,200 non-covered restaurants) + (5% volunteer × 49,900 non-covered grocery, convenience, and general merchandise stores)] (Refs. 44 and 45). We estimate it will require approximately 2 hours per initial registration. Given 10,678 establishments and one initial registration per establishment at 2 hours per registration, we estimate the initial hourly burden for these establishments is 21,356 hours (10,678 establishments × 1 initial registration per establishment × 2 hours per registration). Annualizing

this value over 3 years yields 7,118 hours per year (10,678 establishments/3 years × 1 initial registration per establishment × 2 hours per registration). (10,678 establishments/3 years = 3,559 establishments per year.)

We expect that renewal registrations will require substantially less time because establishments are expected to be able to affirm or update the existing information in an online account in a way similar to other FDA firm registration systems. We estimate that re-registration will take 30 minutes (0.5 hours) for each registrant. This would indicate that biennial registration would impose a burden of 5,340 hours (10,678 establishments × 0.5 hours) every 2 years, or 2,670 hours every year (10,678 establishments/2 years × 0.5 hours).

B. Recordkeeping Requirements

The preamble to the proposed rule provided an estimate of the recordkeeping burden, which consisted of the burden associated with nutrition analysis and the burden associated with generating, providing, or maintaining records. Upon further consideration, we have omitted the burden estimate associated with generating or maintaining records previously estimated in the proposed rule because the rule does not require restaurants and similar retail food establishments to generate or maintain records. This section now includes only the burden estimate associated with providing information substantiating nutrient values of standard menu items to FDA as required by the final rule. Further, as discussed in section C of this analysis, we have included a burden estimate for nutrition analysis as part of the third party disclosure burden, since the total time, effort, or financial resources expended by covered establishments to declare nutrition information likely includes time, effort, or financial resources to determine the nutrition content of covered menu items.

Description of Respondents

The likely respondents to this information collection are restaurants and similar retail food establishments that are subject to the Federal requirements of this rule or that volunteer to be subject to the rule. These establishments include chain retail food establishments and eating and drinking places such as full- and limited-service restaurants, snack bars (including, for example, ice cream, donut, and bagel shops and similar establishments), cafeterias and drinking places, and managed food service facilities. Chain retail food establishments would also include some grocery stores, supermarkets, convenience stores, general merchandise stores, lodging facilities, recreational venues, sports venues, performing arts venues, and movie theaters (Ref. 46).

Description

The paperwork burden for the recordkeeping requirements of the final rule is to provide substantiation of the nutrient values of standard menu items to FDA. The likely respondents for the nutrition analysis are restaurants and similar retail food establishments that are subject to the Federal requirements of this rule or that volunteer to be subject to the rule. These establishments must produce records with information substantiating nutrient values for their standard menu items.

The likely respondents are the universe of retail food establishments and retail chains that are covered by the final rule. Our estimate includes eating and drinking places such as full- and limited-service restaurants, snack bars including, for example, ice cream, donut, and bagel shops and similar establishments, cafeterias and drinking places, and managed food service facilities. Covered establishments also include some grocery stores, supermarkets, convenience stores, general merchandise stores, lodging facilities, recreational venues, sports venues, performing arts venues, and movie theaters.

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

21 CFR part 101	Number recordkeepers	Annual frequency per recordkeeper	Total annual records	Hours per record	Total hours
Initial Burden (Annualized over 3 years)					
§ 101.8(c)(2)(i)(A) Initial Nutrition Analysis Records	69,017	1	69,017	0.25 (15 minutes) ..	17,254
Annual Burden					
§ 101.8(c)(2)(i)(A) Recurring Nutrition Analysis Records.	30,059	1	30,059	0.25 (15 minutes) ..	7,515
Total Burden Hours	.....	.....	.....	.....	24,769

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Initial Nutrition Analysis

We estimate the annual number of the largest restaurant chains that will need to produce substantiation of their standard menu items to be 541 (503 covered restaurant chains + 38 voluntary restaurant chains) with an average of 117 unique menu items that will require an initial nutrition analysis. This leads to 63,297 (541 chains × 117 items) individual chains-specific restaurant records. In addition to chain-level nutrition analysis, each individual restaurant establishment will likely have a small variety of standard menu items that are unique to the individual establishment. We estimate there are 11,684 restaurants establishments (10,866 covered + 818 voluntary) with establishment-specific items. Each of these restaurant establishments has an average of five establishment-specific menu items. This leads to 58,420 (11,684 establishments × 5 items) individual establishment-specific restaurant records.

In addition to restaurants, other similar retail food establishments have both chain-specific and establishment-specific menu items. Other covered retail food establishments include: Grocery stores, supermarkets, convenience stores, general merchandise stores, lodging facilities, recreational venues, sports venues, performing arts venues, and movie theaters. We estimate there are 691 grocery, convenience, and general merchandise (GCGM) store chains (660 covered + 31 voluntary) with an average of 40 menu items each (= 27,640 records); 5,309 GCGM establishments

(5,060 covered + 249 voluntary) with an average of 5 establishment-specific menu items each (= 26,545 records); 50 managed food service (MFS) chains with an average of 80 menu items (= 4,000 records); 450 MFS establishments with an average of 5 establishment-specific menu items (= 2,250 records); 100 lodging chains with an average of 40 menu items (= 4,000 records); 620 lodging establishments with an average of 5 establishment-specific menu items (= 3,100 records); 250 sports, recreation and entertainment (SRE) chains with an average of 59 menu items (= 14,750 records); and 610 SRE establishments with an average of 5 establishment-specific menu times (= 3,050 records). In total, we estimate there are 207,052 records (63,297 restaurant chain-level + 58,420 restaurant establishment-level + 27,640 GCGM chain-level + 26,545 GCGM establishment-level + 4,000 MFS chain-level + 2,250 MFS establishment-level + 4,000 lodging chain-level + 3,100 lodging establishment-level + 14,750 SRE chain-level + 3,050 SRE establishment-level). Annualized over 3 years, this value yields 69,017 (= 207,052 records/3 years) per year. We estimate that each nutrition analysis will require a burden of 15 minutes to produce each record. We estimate the total recordkeeping burden for the initial nutrition analysis to be 17,254.25 hours (= 69,017 records × 0.25 hours per record).

Recurring Nutrition Analysis

From Mintel Menu Insights data, we estimate that restaurant chains introduced, on average, 24 new menu items in 2009 (Ref. 47). Because the final requirements do not apply to temporary menu items, daily specials, and foods that are part of a customary market test, only a fraction of these items will need nutrition analysis. We estimate that existing restaurant chains or individual establishments would need new nutrition analysis for 25 percent of new standard menu items, or six new standard menu items per year. If in addition to these new standard menu items, chains need nutrition analysis on 6 reformulated standard menu items, there would be a total of 12 nutrition analyses per chain needed on an annual basis. Thus we estimate there will be 26,904 annual records associated with new or reformulated items of covered chains [= (1,151 restaurant chains + 691 GCGM chains + 50 MFS chains + 100 lodging chains + 250 SRE chains) × 12 menus items].

In addition we estimate that each year there will be the number of covered chains to increase in each category as companies expand. As discussed in the final RIA, each year there will be some existing non-covered chains that, through expansion of their business, will become subject to the rule's requirements (for example, a chain expanding from 19 to 20 locations). We estimate there will be 20 new restaurant chains, each with an average of 117 menu items; 5 new GCGM chains each with an average of 40 menu items; 3 new MFS chains each with an average of 80 menu items; 2 new lodging chains each with an average of 40 menu items; 5 new SRE chains each with an average of 59 menu items. Thus we estimate there will be 3,155 annual records [= (20 restaurants × 117 items) + (5 GCGM × 40 items) + (3 MFS × 80 items) + (2 lodging × 40 items) + (5 SRE × 59 items] associated with nutrition analysis for new covered chains.

Based on data from FDA's Recordkeeping Cost Model, we estimate that it will take approximately 15 minutes per standard menu item for providing the information of nutrition analysis to FDA (Ref. 48). We estimate the total recurring recordkeeping burden for the nutrition analysis to be 7,515 hours [(26,899 records for new/reformulated standard menu items under existing chains + 3,155 records for items under new chains) × 0.25 hours per record)].

C. Third-Party Disclosure Requirements

Description of Respondents: Restaurants and similar retail food establishments that are subject to statutory menu labeling requirements or that voluntarily elect to be subject to the Federal requirements by registering with FDA.

Description: There will be five types of third-party disclosure burdens under the rule related to: Initial nutrition analysis, initial menu replacement, chain-level written nutrition information, establishment-level nutrition information, recurring nutrition analysis, and recurring menu replacement.

TABLE 3—ESTIMATED THIRD PARTY DISCLOSURE BURDEN

21 CFR Part 101	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total operating and maintenance costs
Initial Burden (Annualized over 3 years)						
§ 101.8(c)(2)(i)(A) Initial Nutrition Analysis.	69,017	1	69,017	4	276,068	
§ 101.8(c)(2)(i)(A) Initial Menu Replacement.	106,168	1	106,168	0.5 (30 minutes)	53,084	$248,767,000
§ 101.8(c)(2)(i)(A) Written Nutrition Information Chain-level.	1,632	1	1,632	3	4,896	
§ 101.8(c)(2)(i)(A) Written Nutrition Information Establishment-level.	18,673	1	18,673	0.5 (30 minutes)	9,337	
Annual Burden						
§ 101.8(c)(2)(i)(A) Recurring Nutrition Analysis.	30,054	1	30,054	4	120,216	
§ 101.8(c)(2)(i)(A) Recurring Menu Replacement.	700	1	700	0.5 (30 minutes)	350	$529,000
Total					463,951	$249,296,000

Initial Nutrition Analysis

The first burden is the time and effort expended by restaurants and other retail food establishments to determine the nutrition content of their covered menu items, which we refer to as ''Nutrition Analysis.'' A nutrition analysis entails the burden of determining nutrition content for covered and voluntary establishment menus by analyzing the food product and summarizing the nutritional information results. Note that the recordkeeping portion of this burden was estimated in the previous subsection.

Our estimate for the annual number of the restaurant and similar retail food chains and individual establishments that will be burdened with initial nutrition analysis is identical to our estimate for the chains and establishments under the recordkeeping subsection. The total number of respondents estimated for the third-party disclosure burden of initial nutrition analysis is 207,052. Annualized over 3 years, this value becomes 69,017. We estimate that each nutrition analysis will require a burden of 4 hours (this estimate of 4 hours was used in the final RIA (Ref. 42)), thus total burden for the initial nutrition analysis is 276,068 hours (207,052 records/3 years × 4 hours per record).

Recurring Nutrition Analysis

The second burden is the time and effort expended by restaurants and other retail food establishments in recurring nutrition analysis. As discussed in the recordkeeping subsection of this PRA, recurring nutrition analysis will be required for new and reformulated standard menu items. Our estimate for the annual number of the restaurant and similar retail food chains and individual establishments that will be burdened with recurring nutrition analysis is identical to our estimate for the chains and establishments under the recordkeeping subsection. The total number of respondents estimated for the third-party disclosure burden of recurring nutrition analysis is 30,054. We estimate that each nutrition analysis will require a burden of 4 hours (this estimate of 4 hours was used in the final RIA (Ref. 42)), thus total third party disclosure burden recurring nutrition analysis is 120,216 hours (30,054 records × 4 hours per record).

Initial Menu Replacement

The third burden is for the time expended by restaurants and similar retail food establishments to physically produce and install the menus, menu boards that include the new calorie declarations, which we refer to as ''Calorie Declaration Signs.'' As described in the final RIA (Ref. 42), chain retail food establishments will need to redesign and replace their existing menus and menu boards in order to comply with the final requirements. For full service restaurants and drinking places with only personal menus and no menu boards, this burden will be relatively low. Most menus are replaced frequently anyway as they wear out, are lost, or as prices and menu items change. For many of these establishments, the burden of updating menus to comply with the final requirements would be limited to design and associated administrative hours.

The longer lifespan of menu boards in limited-service eating places would likely require the redesign of menu/menu boards and the replacement of one or more menu boards. In addition, some chains would need to update self-serve and display signs. The number of menus that an establishment will keep on hand is highly variable. A full-service restaurant, where each order is placed using a menu, will need more than a quick-service establishment that uses menus just for takeout orders. The number of menus is also tied to the seating capacity of the restaurant, and whether the menu is laminated or paper. Because paper menus are more fragile and cheaper to print in bulk, an establishment may keep a large reserve in stock, whereas establishments using more durable and expensive laminated menus may only keep a few extra on hand. Estimates for the burden of updating menu boards, other major displays that serve as menus, such as electronic displays, or major materials needed to disclose calories for self-serve or displayed foods to comply with the final requirements, will vary widely across chains and establishments because of different menu board and display types.

As described in the RIA, we estimate that the average full-service restaurant establishment must discard and reprint one menu for each seat, plus 10 extra, for a total of 91 menus per restaurant each year. We estimate that GCGM stores have an average of two menu boards per establishment based on public comments that we received. We estimate that MFS and SRE establishments will each have an average of one menu board. Lodging establishments generally have menus instead of menu boards, and we estimate the menu replacement burden for establishments in the lodging sector to be 87 menu replacements per establishment. Since each covered and voluntarily registered establishment will need to replace menus and/or menu boards, we estimate this total value to be 318,505 (= 248,610 restaurants + 53,095 GCGM + 4,500 MFS + 6,200 lodging + 6,100 SRE). (In the previous calculation, 248,610 restaurants = 231,200 covered restaurants + 17,410 voluntary; and 53,095 GCGM = 50,600 covered + 2,495 voluntary.) Annualized over 3 years, this value becomes 106,168 (= 318,505/3 years). We estimate the labor burden for ordering new menus and menu boards to be 30 minutes (0.5 hours) per establishment. Thus the total burden for initial menu replacement is 53,084 hours per year. At an average wage (which includes an extra 50 percent to account for overhead costs and employee benefits) of $30 per hour for managers across the covered industries, the labor burden comes to $1,593,000 (= 53,084 hours × $30 per hour). In the final RIA (Ref. 42), we estimated the total average costs associated with initial menu replacement to be $250.36 million. This value takes into consideration costs of menu/menu board design, printing, and installation. Subtracting the labor costs of ordering new menus, $1,593,000, from the total costs for initial menu replacement, $250,360,000, yields total initial operating and maintenance costs of $248,767,000.

Recurring Menu Replacement for New Chains

The fourth burden is for the time expended by new restaurants and similar retail food establishments to physically replace menus and menu boards that include the new calorie declarations. All restaurants and similar retail food chains that become covered as the number of their associated establishments grows beyond the coverage threshold of 20 will need to replace their menus and menu boards. We estimated in the final RIA (Ref. 42) that the annual number of new covered restaurants and similar retail food establishments is 700. Again, we estimate the labor burden for ordering new menus and menu boards to be 30 minutes (0.5 hours) per establishment. Thus the total annual burden for recurring menu replacement is 350 hours per year. At an average wage (which includes an extra 50 percent in overhead costs and employee benefits) of $30 per hour for managers across the covered industries, the recurring labor burden comes to $11,000 (= 350 hours × $30 per hour). In the final RIA, we estimated the total average annual operating and maintenance costs associated with recurring menu replacement to be $540,000. This value

takes into consideration costs of menu/menu board design, printing, and installation. Subtracting the recurring labor costs of ordering new menus, $11,000, from the total costs for recurring menu replacement of $540,000, yields total recurring operating and maintenance costs of $529,000.

Written Nutrition Information

The fifth burden is for the time expended by restaurants and similar retail food establishments to make written nutrition information available to customers upon request. The number of chains (and associated establishments) that do not already provide this information was estimated in the recordkeeping subsection under initial nutrition analysis, or 1,632 chains (503 covered restaurant + 38 voluntary restaurant + 660 covered GCGM + 31 voluntary GCGM + 50 covered MFS + 100 covered lodging + 250 covered SRE) and 18,673 establishments with establishment specific-menu items (10,866 covered restaurant + 818 voluntary restaurant + 5,060 covered GCGM + 249 voluntary GCGM + 450 covered MFS + 620 covered lodging + 610 covered SRE). We estimate the time it takes to provide written nutrition information at the chain level to be 3 hours per respondent. Since the average number of establishment-specific menu items is only five per establishment, we estimate the time it takes to provide written nutrition information at the establishment level (for those menu items that are specific only to the establishment) to be 30 minutes per respondent. Thus the total burden hours for chain-level and establishment level written nutrition information disclosure are 4,896 and 9,336.5 hours, respectively. Therefore the total third party disclosure burden for the rule is 463,950.5 hours with total operating and maintenance costs of $249,296,000.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB Control Number 0910–NEW, and title ''Information Collection Provisions of the Final Rule on Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments.'' Also include the FDA docket number found in brackets in the heading of this document.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have resubmitted the information collection provisions of this final rule to OMB for review, because the final rule provides additional modifications to § 101.11. These requirements will not be effective until we obtain OMB approval. Interested persons are requested to submit comments regarding information collection to OMB (see **DATES** and **ADDRESSES**).

Prior to the effective and compliance date of this final rule, we will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

XXVII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision that preempts ''any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) [of the FD&C Act] [21 U.S.C. 343(q)]'', except that this provision does not apply ''to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 403(q)(5)(H)(ix) [of the FD&C Act].'' In the proposed rule, we provided an interpretation of the preemptive provisions of section 4205 of the ACA, as well as an alternative interpretation (76 FR 19192 at 19203). (21 U.S.C. 343–1(a)(4)). The final rule creates requirements for nutrition labeling of food under section 403(q) of the FD&C Act that would preempt certain non-identical State and local nutrition labeling requirements.

Section 4205 of the ACA also includes a Rule of Construction providing that ''Nothing in the amendments made by [section 4205] shall be construed—(1) to preempt any provision of State or local law, unless such provision establishes or continues into effect nutrient content disclosures of the type required under section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)(5)(H)] (as added by subsection(b)) and is expressly preempted under subsection (a)(4) of such section; (2) to apply to any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food; or (3) except as provided in section 403(q)(5)(H)(ix) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)(5)(H)(ix)] (as added by subsection (b)), to apply to any restaurant or similar retail food establishment other than a restaurant or similar retail food establishment described in section 403(q)(5)(H)(i) of such Act.'' (See Pub. L. 111–148, Sec. 4205(d), 124 Stat. 119, 576 (2010).)

We interpret the provisions of section 4205 of the ACA related to preemption to mean that States and local governments may not impose nutrition labeling requirements for food sold in a covered establishment, as defined in § 101.11(a), unless the State or local requirements are identical to the Federal requirements. In other words, States and localities cannot have additional or different nutrition labeling requirements for food sold either in (1) chain retail food establishments or (2) restaurants and similar retail food establishments not subject to the requirements of section 403(q)(5)(H) of the FD&C Act that voluntarily elect to be subject to the requirements by registering biannually under section 403(q)(5)(H)(ix).

Otherwise, for certain food that is not subject to the nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act, States and localities may establish or continue to impose nutrition labeling requirements. First, States and localities can have nutrition labeling requirements for food sold in restaurants or similar retail food establishments that are not part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items that have not voluntarily registered under section 403(q)(5)(H)(ix) of the FD&C Act.

Second, States and localities can have nutrition labeling requirements for foods offered for sale in other establishments described in sections

403(q)(5)(A)(i) or (ii) of the FD&C Act that are exempt from the nutrition labeling requirements of sections 403(q)(1) to (q)(4) of the FD&C Act under section 403(q)(5)(A)(i) or (ii) of the FD&C Act, provided that such food is not required to have nutrition labeling under section 403(q)(5)(H) of the FD&C Act. For example, certain foods sold in schools and transportation carriers would not be required to have nutrition labeling under sections 403(q)(1) to (q)(4) of the FD&C Act (see section 403(q)(5)(A)(i) and (ii) of the FD&C Act and § 101.9(j)(2) and (j)(3)), or under section 403(q)(5)(H) of the FD&C Act because these establishments are not covered establishments within the meaning of § 101.11(a). Under our interpretation of the Rule of Construction in section 4205(d)(1) of the ACA, nutrition labeling for food sold from such establishments would not be ''nutrient content disclosures of the type required under section 403(q)(5)(H)(viii) [of the FD&C Act]'' and, therefore, would not be preempted. As a result, States and localities would be able to continue to require nutrition labeling for foods sold from establishments that are exempt from the nutrition labeling requirements of section 403(q)(1) to (q)(4) of the FD&C Act and not subject to nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act.

In addition, the express preemption provisions of section 403(A)(a)(4) of the FD&C Act do not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food.

The preamble to the proposed rule (76 FR 19192 at 19229 to 19230) described an alternative interpretation of the preemption provisions of section 4205 of the ACA that could leave less room for States and localities to require nutrition labeling for food sold in restaurants or similar retail food establishments. Under this alternative interpretation, State or local nutrition labeling requirements for food sold in establishments that are not ''restaurants or similar retail food establishments,'' would be ineligible for the exception to the preemption in section 403(A)(a)(4) of the FD&C Act, because that exception by its literal terms only covers nutrition labeling requirements for food offered for sale in certain restaurants or similar retail food establishments, specifically those not subject to the nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act. Under this alternative interpretation, States and localities could not have nutrition labeling requirements for certain foods offered for sale in non-restaurants and similar retail food establishments unless they successfully petitioned us. Federal law provides that, upon petition, FDA may exempt State or local requirements from the express preemption provisions of section 403A(a)(4) of the FD&C Act under certain conditions. (See 21 U.S.C. 343–1(b).) We have issued regulations at § 100.1 (21 CFR 100.1) describing the petition process that is available to State and local governments to request such exemptions from preemption.

In addition, under this alternative interpretation, there would be foods in certain establishments for which the Federal Government has not required nutrition labeling and for which States and localities would also be precluded from establishing such labeling requirements unless they successfully petitioned us and a rulemaking was completed. This approach would risk creating a regulatory gap that would be inconsistent with the purposes of section 4205 of the ACA. It would also impose a restriction and burden on the States and localities that is inconsistent with the Federalism principles expressed in Executive Order 13132, as well as a substantial administrative burden on FDA in the event States petition for exemption.

We requested comment on our interpretation of section 4025 of the ACA related to preemption, as well as the alternative interpretation. We also requested comment on the use of the petition process in this context and on other potential interpretations that interested persons could identify as appropriate given both the preemption-related language of section 4205 of the ACA and the statutory goals.

(Comment 157) Several comments agreed with our interpretation of the preemption provisions of section 4205 of the ACA. A few of these comments recommended that the final rule include an explicit statement that the scope of the law's preemptive effect is coextensive with the law's nutrition labeling requirements; that is, the only State and local provisions that are preempted are those that explicitly require the type of menu labeling set forth in section 4205 of the ACA at a covered establishment. For example, the comments stated that if we decide not to cover movie theaters, hospitals, and other establishments or decide to exempt alcohol beverages from menu labeling in the final rule, then States and localities can enact laws to cover them. Another comment stated that an express statement about preemption will encourage States and localities to pass laws that fill in the gaps and to pass identical laws.

One comment disagreed with our proposed interpretation of the preemption provisions and its outcome. The comment stated that narrowing the exception for preemption is consistent with Congress' purpose to preempt the growing patchwork of State and local menu labeling laws. In addition, the comment stated that, while the alternative interpretation would result in a ''regulatory gap'' with some establishments not covered by Federal, State, and local menu labeling laws, Congress could amend the FD&C Act, if it chose to do so.

(Response 157) We agree with the comments asserting that the preemptive effect of the Federal menu labeling requirements of section 4205 of the ACA is limited to State and local requirements that impose additional or different nutrition labeling requirements for food that is covered by the Federal requirements of section 403(q)(5)(H) of the FD&C Act and § 101.11. We also agree that the alternative interpretation described in the proposed rule (76 FR 19192 at 19230) would restrict State and local authorities and create a regulatory gap that would be inconsistent with the purposes and language of section 4205 of the ACA and the Federalism principles expressed in Executive Order 13132.

We disagree with the comment that suggested that the alternative interpretation is more consistent with congressional intent to preempt the ''patchwork'' of State and local laws on menu labeling and that the solution for the ''regulatory gap'' under that interpretation would be for Congress to amend the FD&C Act again. Congress did create a uniform national menu labeling scheme for certain foods in certain facilities described in section 4205 of the ACA. However, nothing in the legislative history suggests that Congress intended to create a category of foods in establishments for which neither the Federal Government nor State or local governments could require menu labeling. We think it is more consistent with the purposes of section 4205 of the ACA, which provides valuable nutrition information to consumers, to allow State and local governments to require menu labeling for food not covered by Federal law. The language of section 4205(c) of the ACA amending section 403A of the FD&C Act is consistent with our final interpretation. This amendment includes an exception from preemption for food sold in restaurants or similar retail food establishments that are not restaurants or establishments subject to the requirements of 403(q)(5)(H) of the FD&C Act.

For these reasons, we interpret the provisions of section 4205 of the ACA related to preemption to mean that State and local governments may not establish or continue in effect nutrition labeling requirements for food covered by the Federal requirements of section 403(q)(5)(H) of the FD&C Act and § 101.11, unless the State or local requirements are identical to the Federal requirements of section 403(q)(5)(H) of the FD&C Act and § 101.11. In other words, States and localities cannot have additional or different nutrition labeling requirements for food sold either from: (1) Chain retail food establishments; or (2) restaurants and similar retail food establishments not otherwise subject to the requirements of section 403(q)(5)(H) and § 101.11 who voluntarily elect to be subject to those requirements by registering biannually with FDA in accordance with section 403(q)(5)(H)(ix) of the FD&C Act and § 101.11(d). For food sold in restaurants and similar retail establishments not subject to the nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act, States and localities may impose nutrition labeling requirements.

(Comment 158) Several comments agreed with our interpretation of the Rule of Construction. One comment agreed that warning statements are not preempted but asked us to clarify that this does not mean just microbiological hazards.

A few comments recommended that we codify the Rule of Construction. The comments asserted that the absence of codified provisions in the rule regarding the Rule of Construction could lead to confusion in properly interpreting the statute. The comments maintained that the lack of codified provisions in the rule for a similar Rule of Construction in the NLEA (see 21 U.S.C. 343–1 note) has led to confusion and to court decisions that have not taken that rule into account. The comments maintained that ensuring that the Rule of Construction is explicitly set out in Title 21 of the Code of Federal Regulations could help to avoid similar problems with the menu labeling law.

(Response 158) With respect to our interpretation of the Rule of Construction in section 4205(d) of the ACA, we reiterate that State or local requirements for statements in food labeling providing for warnings concerning food safety are not preempted. We agree with the comment that food safety in this context is not limited to microbiological hazards. We are not persuaded by the comments suggesting that we add a codified statement to § 101.11 restating the Rule of Construction at section 4205(d) of the ACA. We have highlighted the existence of the Rule of Construction and have explained our interpretation of section 4205(d) of the ACA both in the preamble to the proposed rule and in the preamble to this final rule. We do not think that codifying the Rule of Construction in section 4205(d) in our regulations is needed either to prevent confusion in interpreting the statute or to assure that courts consider section 4205(d) when appropriate.

(Comment 159) Some comments asked us to address the meaning of ''identical'' in section 403A(a)(4) of the FD&C Act, which excludes from preemption State and local requirements that are identical to Federal requirements under section 403(q) of the FD&C Act. The comments recommended that the final rule explicitly state that ''identical'' refers to the effect of the law and does not mean that a State or local requirement must be identical in wording of the law.

(Response 159) In response to the comments asserting that we revise the rule to clarify the meaning of ''identical'' within the context of section 403A(a)(4) of the FD&C Act, we note that we have already issued a regulation at § 100.1 that explains the meaning of ''not identical to'' in the context of section 403A of the FD&C Act in describing the petition process available to State and local governments to request an exemption from the express preemption provisions of section 403A of the FD&C Act under section 403A(b). Section 100.1(c)(4) provides in relevant part that, within the context of section 403A of FD&C Act, ''not identical to'' does not refer to the specific words in the State or local requirement but instead means that the State or local requirement directly or indirectly imposes obligations or contains provisions concerning the labeling of food that: (1) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 403 of the FD&C Act; or (2) differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 403 of the FD&C Act.

Accordingly, a State or local nutrition labeling requirement for food covered by the requirements of section 403(q)(5)(H) of the FD&C Act and § 101.11 that directly or indirectly imposes obligations or contains labeling provisions that: (1) Are not imposed by or contained in section 403(q) of the FD&C Act and § 101.11; or (2) differ from those specifically imposed by or contained in section 403(q) of the FD&C Act and § 101.11 would be ''not identical to'' the Federal requirements and therefore would be preempted under section 403A(a)(4) of the FD&C Act. Because the meaning of the phrase ''not identical to,'' within the context of section 403A of the FD&C Act, is already described in § 100.1 and is further explained here, we decline to revise the rule to clarify the meaning of ''identical'' as suggested by the comments.

(Comment 160) A few comments recommended that we support development of State and local laws that are identical. The comments recommended that we help the States and localities by making staff available to help assess the proposed language of State or local law for potential conflicts with Federal law and providing model legislation, which should be made part of the Model Food Code.

(Response 160) As discussed in section XXIV, a State or local jurisdiction may establish requirements, identical to those established in this rule, in its own food codes and then enforce its own food codes. Whether we can help States and localities assess the proposed language of State or local law for potential conflicts with Federal law will depend on resources available at the time of any requests for such assistance. However, at this time, we do not expect to have resources to provide model legislation for use by States and localities. We recommend that States and localities who wish to establish requirements, in their own food codes, identical to those established in this rule adapt § 101.11 for their own use.

(Comment 161) One comment asked us to describe the basis on which establishments that opt into the program can be assured that preemption applies. The comment asserted that if a facility complies with the Federal requirements under its food service contract as agreed to by the Federal Government, that establishment must be fully protected from State and local menu labeling action. The comment also stated that a facility's compliance with the terms of a Federal Government contract must suffice as certification that the facility is in compliance with all FDA menu labeling provisions and the facility should be permitted to opt into our program without any additional requirements.

(Response 161) As provided in 403(q)(5)(H)(ix) of the FD&C Act, authorized officials of restaurants and similar retail establishments that are not subject to the requirements of section 403(q)(5)(H) may elect to be subject to those requirements by registering biannually with FDA, as specified in § 101.11(d). Under section 403A(a)(4) of

the FD&C Act, an establishment that ''complies with the voluntary provision of nutrition information requirements of 403(q)(5)(H)(ix)'' brings itself within the scope of Federal preemption of State and local laws. The comment appears essentially to be seeking FDA's assurances that a facility's compliance with the terms of a Federal contract to provide food services would (1) suffice for ''opting in'' to the voluntary program and (2) guarantee that State and local menu labeling action against the facility is prohibited. We decline to provide such assurances. The requirements for voluntarily ''opting in'' to be subject to the Federal menu labeling requirements are set forth in § 101.11(d). Preemption of certain State and local requirements follows from voluntarily becoming subject to the requirements of § 101.11. The effects of following the terms of Federal contracts to procure food services are outside the scope of this rulemaking.

XXVIII. Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XXIX. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified all the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**).

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List of Subjects

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 11 and 101 are amended as follows:

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 1. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 2. Section 11.1 is amended by adding paragraph (g) to read as follows:

§ 11.1 Scope.

* * * * *

(g) This part does not apply to electronic signatures obtained under § 101.11(d) of this chapter.

PART 101—FOOD LABELING

■ 3. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 4. Section 101.9 is amended by revising paragraph (j)(1)(i), the introductory text of paragraphs (j)(2) and (3), and the first sentence of paragraph (j)(4) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(j) * * *

(1)(i) Food offered for sale by a person who makes direct sales to consumers (*e.g.,* a retailer) who has annual gross sales made or business done in sales to consumers that is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers of not more than $50,000, *Provided,* That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section, § 101.10, or § 101.11, as applicable.

* * * * *

(2) Except as provided in § 101.11, food products that are:

* * * * *

(3) Except as provided in § 101.11, food products that are:

* * * * *

(4) Except as provided in § 101.11, foods that contain insignificant amounts of all of the nutrients and food components required to be included in the declaration of nutrition information under paragraph (c) of this section, *Provided,* That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. * * *

* * * * *

■ 5. Section 101.10 is revised to read as follows:

§ 101.10 Nutrition labeling of restaurant foods whose labels or labeling bear nutrient content claims or health claims.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (*e.g.,* ''low fat, this meal provides less than 10 grams of fat'') may serve as the functional equivalent of complete nutrition information as described in § 101.9. For the purposes of this section, restaurant food includes two categories of food. It includes food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments. It also includes food which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in the previous sentence, and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment. For standard menu items that are offered for sale in covered establishments (as defined in § 101.11(a)), the information in the written nutrition information required by § 101.11(b)(2)(ii)(A) will serve to meet the requirements of this section. Nutrient levels may be determined by nutrient databases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

■ 6. Section 101.11 is added to subpart A to read as follows:

§ 101.11 Nutrition labeling of standard menu items in covered establishments.

(a) *Definitions.* The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this section. In addition, for purposes of this section:

Authorized official of a restaurant or similar retail food establishment means the owner, operator, agent in charge, or other person authorized by the owner, operator, or agent in charge to register the restaurant or similar retail food establishment, which is not otherwise subject to section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act, with FDA for the purposes of paragraph (d) of this section.

Combination meal means a standard menu item that consists of more than one food item, for example a meal that includes a sandwich, a side dish, and a drink. A combination meal may be represented on the menu or menu board in narrative form, numerically, or pictorially. Some combination meals may include a variable menu item or be a variable menu item as defined in this paragraph where the components may vary. For example, the side dish may vary among several options (*e.g.,* fries, salad, or onion rings) or the drinks may vary (*e.g.,* soft drinks, milk, or juice) and the customer selects which of these items will be included in the meal.

Covered establishment means a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, *e.g.,* individual franchises) and offering for sale substantially the same menu

items, as well as a restaurant or similar retail food establishment that is registered to be covered under paragraph (d) of this section.

Custom order means a food order that is prepared in a specific manner based on an individual customer's request, which requires the covered establishment to deviate from its usual preparation of a standard menu item, *e.g.,* a club sandwich without the bacon if the establishment usually includes bacon in its club sandwich.

Daily special means a menu item that is prepared and offered for sale on a particular day, that is not routinely listed on a menu or menu board or offered by the covered establishment, and that is promoted by the covered establishment as a special menu item for that particular day.

Doing business under the same name means sharing the same name. The term ''name'' refers to either:

(i) The name of the establishment presented to the public; or

(ii) If there is no name of the establishment presented to the public (*e.g.,* an establishment with the generic descriptor ''concession stand''), the name of the parent entity of the establishment. When the term ''name'' refers to the name of the establishment presented to the public under paragraph (i) of this definition, the term ''same'' includes names that are slight variations of each other, for example, due to the region, location, or size (*e.g.,* ''New York Ave. Burgers'' and ''Pennsylvania Ave. Burgers'' or ''ABC'' and ''ABC Express'').

Food on display means restaurant-type food that is visible to the customer before the customer makes a selection, so long as there is not an ordinary expectation of further preparation by the consumer before consumption.

Food that is part of a customary market test means food that appears on a menu or menu board for less than 90 consecutive days in order to test consumer acceptance of the product.

Location means a fixed position or site.

Menu or *menu board* means the primary writing of the covered establishment from which a customer makes an order selection, including, but not limited to, breakfast, lunch, and dinner menus; dessert menus; beverage menus; children's menus; other specialty menus; electronic menus; and menus on the Internet. Determining whether a writing is or is part of the primary writing of the covered establishment from which a customer makes an order selection depends on a number of factors, including whether the writing lists the name of a standard menu item (or an image depicting the standard menu item) and the price of the standard menu item, and whether the writing can be used by a customer to make an order selection at the time the customer is viewing the writing. The menus may be in different forms, *e.g.,* booklets, pamphlets, or single sheets of paper. Menu boards include those inside a covered establishment as well as drive-through menu boards at covered establishments.

Offering for sale substantially the same menu items means offering for sale a significant proportion of menu items that use the same general recipe and are prepared in substantially the same way with substantially the same food components, even if the name of the menu item varies, (*e.g.* ''Bay View Crab Cake'' and ''Ocean View Crab Cake''). ''Menu items'' in this definition refers to food items that are listed on a menu or menu board or that are offered as self-service food or food on display. Restaurants and similar retail food establishments that are part of a chain can still be offering for sale substantially the same menu items if the availability of some menu items varies within the chain. Having the same name may indicate, but does not necessarily guarantee, that menu items are substantially the same.

Restaurant or similar retail food establishment means a retail establishment that offers for sale restaurant-type food, except if it is a school as defined by 7 CFR 210.2 or 220.2.

Restaurant-type food means food that is:

(i) Usually eaten on the premises, while walking away, or soon after arriving at another location; and

(ii) Either:

(A) Served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments; or

(B) Processed and prepared primarily in a retail establishment, ready for human consumption, of the type described in paragraph (ii)(A) of this definition, and offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment.

Self-service food means restaurant-type food that is available at a salad bar, buffet line, cafeteria line, or similar self-service facility and that is served by the customers themselves. Self-service food also includes self-service beverages.

Standard menu item means a restaurant-type food that is routinely included on a menu or menu board or routinely offered as a self-service food or food on display.

Temporary menu item means a food that appears on a menu or menu board for less than a total of 60 days per calendar year. The 60 days includes the total of consecutive and non-consecutive days the item appears on the menu.

Variable menu item means a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item.

(b) *Requirements for nutrition labeling for food sold in covered establishments*—(1) *Applicability.* (i) The labeling requirements in this paragraph (b) apply to standard menu items offered for sale in covered establishments.

(ii)(A) The labeling requirements in this paragraph (b) do not apply to foods that are not standard menu items, including:

(*1*) Items such as condiments that are for general use, including those placed on the table or on or behind the counter; daily specials; temporary menu items; custom orders; food that is part of a customary market test; and

(*2*) Self-service food and food on display that is offered for sale for less than a total of 60 days per calendar year or fewer than 90 consecutive days in order to test consumer acceptance.

(B) The labeling requirements of paragraph (b)(2)(iii) of this section do not apply to alcoholic beverages that are foods on display and are not self-service foods.

(2) *Nutrition information.* (i) Except as provided by paragraph (b)(2)(i)(A)(*8*) of this section, the following must be provided on menus and menu boards:

(A) The number of calories contained in each standard menu item listed on the menu or menu board, as usually prepared and offered for sale. In the case of multiple-serving standard menu items, this means the calories declared must be for the whole menu item listed on the menu or menu board as usually prepared and offered for sale (*e.g.,* ''pizza pie: 1600 cal''); or per discrete serving unit as long as the discrete serving unit (*e.g.,* pizza slice) and total number of discrete serving units contained in the menu item are declared on the menu or menu board, and the menu item is usually prepared and offered for sale divided in discrete serving units (*e.g.,* ''pizza pie: 200 cal/slice, 8 slices''). The calories must be declared in the following manner:

(*1*) The number of calories must be listed adjacent to the name or the price of the associated standard menu item, in a type size no smaller than the type size of the name or the price of the

associated standard menu item, whichever is smaller, in the same color, or a color at least as conspicuous as that used for the name of the associated standard menu item, and with the same contrasting background or a background at least as contrasting as that used for the name of the associated standard menu item.

(*2*) To the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero.

(*3*) The term ''Calories'' or ''Cal'' must appear as a heading above a column listing the number of calories for each standard menu item or adjacent to the number of calories for each standard menu item. If the term ''Calories'' or ''Cal'' appears as a heading above a column of calorie declarations, the term must be in a type size no smaller than the smallest type size of the name or price of any menu item on that menu or menu board in the same color or a color at least as conspicuous as that used for that name or price and in the same contrasting background or a background at least as contrasting as that used for that name or price. If the term ''Calories'' or ''Cal'' appears adjacent to the number of calories for the standard menu item, the term ''Calories'' or ''Cal'' must appear in the same type size and in the same color and contrasting background as the number of calories.

(*4*) Additional requirements that apply to each individual variable menu item:

(*i*) When the menu or menu board lists flavors or varieties of an entire individual variable menu item (such as soft drinks, ice cream, doughnuts, dips, and chicken that can be grilled or fried), the calories must be declared separately for each listed flavor or variety. Where flavors or varieties have the same calorie amounts (after rounding in accordance with paragraph (b)(2)(i)(A)(*2*) of this section), the calorie declaration for such flavors or varieties can be listed as a single calorie declaration adjacent to the flavors or varieties, provided that the calorie declaration specifies that the calorie amount listed represents the calorie amounts for each individual flavor or variety.

(*ii*) When the menu or menu board does not list flavors or varieties for an entire individual variable menu item, and only includes a general description of the variable menu item (*e.g.* ''soft drinks''), the calories must be declared for each option with a slash between the two calorie declarations where only two options are available (*e.g.,* ''150/250 calories'') or as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(*7*) of this section where more than two options are available (*e.g.,* ''100–250 calories'').

(*iii*) When the menu or menu board describes flavors or varieties for only part of an individual variable menu item (such as different types of cheese offered in a grilled cheese sandwich (*e.g.,* ''Grilled Cheese (Cheddar or Swiss)''), the calories must be declared for each option with a slash between the two calorie declarations where only two options are available (*e.g.,* ''450/500 calories'') or as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(*7*) of this section where more than two options are available (*e.g.,* ''450–550 calories'').

(*5*) Additional requirements that apply to a variable menu item that is offered for sale with the option of adding toppings listed on the menu or menu board. When the menu or menu board lists toppings that can be added to a menu item (such as pizza or ice cream):

(*i*) The calories must be declared for the basic preparation of the menu item as listed (*e.g.,* ''small pizza pie,'' ''single scoop ice cream'').

(*ii*) The calories must be separately declared for each topping listed on the menu or menu board (*e.g.,* pepperoni, sausage, green peppers, onions on pizza; fudge, almonds, sprinkles on ice cream), specifying that the calories are added to the calories contained in the basic preparation of the menu item. Where toppings have the same calorie amounts (after rounding in accordance with paragraph (b)(2)(i)(A)(*2*) of this section), the calorie declaration for such toppings can be listed as a single calorie declaration adjacent to the toppings, provided that the calorie declaration specifies that the calorie amount listed represents the calorie amount for each individual topping.

(*iii*) The calories for the basic preparation of the menu item must be declared for each size of the menu item. The calories for each topping listed on the menu or menu board must be declared for each size of the menu item, or declared using a slash between the two calorie declarations for each topping where only two sizes of the menu item are available (*e.g.,* ''adds 150/250 cal'') or as a range for each topping in accordance with the requirements of paragraph (b)(2)(i)(A)(*7*) of this section where more than two sizes of the menu item are available (*e.g.,* ''adds 100–250 cal''). If a slash between two calorie declarations or a range of calorie declarations is used, the menu or menu board must indicate that the variation in calories for each topping arises from the size of the menu item to which the toppings are added.

(*iv*) If the amount of the topping included on the basic preparation of the menu item decreases based on the total number of toppings ordered for the menu item (such as is sometimes the case with pizza toppings), the calories for each topping must be declared as single values representing the calories for each topping when added to a one-topping menu item, specifying that the calorie declaration is for the topping when added to a one-topping menu item.

(*6*) Additional requirements that apply to a combination meal. Except as provided in paragraph (b)(2)(i)(A)(*6*)(*iv*) of this section:

(*i*) When the menu or menu board lists two options for menu items in a combination meal (*e.g.,* a sandwich with a side salad or chips), the calories must be declared for each option with a slash between the two calorie declarations (*e.g.,* ''350/450 calories'').

(*ii*) When the menu or menu board lists three or more options for menu items in a combination meal (*e.g.,* a sandwich with chips, a side salad, or fruit), the calories must be declared as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(*7*) of this section (*e.g.,* ''350–500 calories'').

(*iii*) When the menu or menu board includes a choice to increase or decrease the size of a combination meal, the calorie difference must be declared for the increased or decreased size with a slash between two calorie declarations (*e.g.,* ''Adds 100/150 calories,'' ''Subtracts 100/150 calories'') if the menu or menu board lists two options for menu items in the combination meal, or as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(*7*) of this section (*e.g.,* ''Adds 100–250 calories,'' ''Subtracts 100–250 calories'') if the menu or menu board lists three or more options for menu items in the combination meal.

(*iv*) Where the menu or menu board describes an opportunity for a consumer to combine standard menu items for a special price (*e.g.,* ''Combine Any Sandwich with Any Soup or Any Salad for $8.99''), and the calories for each standard menu item, including each size option as described in paragraph (b)(2)(i)(A)(*6*)(*iii*) of this section if applicable, available for the consumer to combine are declared elsewhere on the menu or menu board, the requirements of paragraphs (b)(2)(i)(A)(*6*)(*i*), (*ii*), and (*iii*) of this section do not apply.

(*7*) Additional format requirements for declaring calories for an individual variable menu item, a combination meal, and toppings as a range, if

applicable. Calories declared as a range must be in the format ''xx–yy,'' where ''xx'' is the caloric content of the lowest calorie variety, flavor, or combination, and ''yy'' is the caloric content of the highest calorie variety, flavor, or combination.

(*8*) Exception for a variable menu item that has no clearly identifiable upper bound to the range of calories: If the variable menu item appears on the menu or menu board and is a self-service food or food on display, and there is no clearly identifiable upper bound to the range, *e.g.,* all-you-can-eat buffet, then the menu or menu board must include a statement, adjacent to the name or price of the item, referring customers to the self-service facility for calorie information, *e.g.,* ''See buffet for calorie declarations.'' This statement must appear in a type size no smaller than the type size of the name or price of the variable menu item, whichever is smaller, and in the same color or a color at least as conspicuous as that used for that name or price, with the same contrasting background or a background at least as contrasting as that used for that name or price.

(*9*) Additional requirements that apply to beverages that are not self-service. For beverages that are not self-service, calories must be declared based on the full volume of the cup served without ice, unless the covered establishment ordinarily dispenses and offers for sale a standard beverage fill (*i.e.,* a fixed amount that is less than the full volume of the cup per cup size) or dispenses a standard ice fill (*i.e.,* a fixed amount of ice per cup size). If the covered establishment ordinarily dispenses and offers for sale a standard beverage fill or dispenses a standard ice fill, the covered establishment must declare calories based on such standard beverage fill or standard ice fill.

(B) The following statement designed to enable consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards: ''2,000 calories a day is used for general nutrition advice, but calorie needs vary.'' For menus and menu boards targeted to children, the following options may be used as a substitute for or in addition to the succinct statement: ''1,200 to 1,400 calories a day is used for general nutrition advice for children ages 4 to 8 years, but calorie needs vary.''; or ''1,200 to 1,400 calories a day is used for general nutrition advice for children ages 4 to 8 years and 1,400 to 2,000 calories a day for children ages 9 to 13 years, but calorie needs vary.''

(*1*) This statement must be posted prominently and in a clear and conspicuous manner in a type size no smaller than the smallest type size of any calorie declaration appearing on the same menu or menu board and in the same color or in a color at least as conspicuous as that used for the calorie declarations and with the same contrasting background or a background at least as contrasting as that used for the calorie declarations.

(*2*) For menus, this statement must appear on the bottom of each page of the menu. On menu pages that also bear the statement required by paragraph (b)(2)(i)(C) of this section, this statement must appear immediately above, below, or beside the statement required by paragraph (b)(2)(i)(C) of this section.

(*3*) For menu boards, this statement must appear on the bottom of the menu board, immediately above, below, or beside the statement required by paragraph (b)(2)(i)(C) of this section.

(C) The following statement regarding the availability of the additional written nutrition information required in paragraph (b)(2)(ii) of this section must be on all forms of the menu or menu board: ''Additional nutrition information available upon request.''

(*1*) This statement must be posted prominently and in a clear and conspicuous manner in a type size no smaller than the smallest type size of any calorie declaration appearing on the same menu or menu board and in the same color or in a color at least as conspicuous as that used for the caloric declarations, and with the same contrasting background or a background at least as contrasting as that used for the caloric declarations.

(*2*) For menus, the statement must appear on the bottom of the first page with menu items immediately above, below, or beside the succinct statement required by paragraph (b)(2)(i)(B) of this section.

(*3*) For menu boards, the statement must appear on the bottom of the menu board immediately above, below, or beside the succinct statement required by paragraph (b)(2)(i)(B) of this section.

(ii) The following nutrition information for a standard menu item must be available in written form on the premises of the covered establishment and provided to the customer upon request. This nutrition information must be presented in the order listed and using the measurements listed, except as provided in paragraph (b)(2)(ii)(B) of this section. Rounding of these nutrients must be in compliance with § 101.9(c). The information must be presented in a clear and conspicuous manner, including using a color, type size, and contrasting background that render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Covered establishments may use the abbreviations allowed for Nutrition Facts for certain packaged foods in § 101.9(j)(13)(ii)(B):

(A)(*1*) Total calories (cal);
(*2*) Calories from fat (fat cal);
(*3*) Total fat (g);
(*4*) Saturated fat (g);
(*5*) *Trans* fat (g);
(*6*) Cholesterol (mg);
(*7*) Sodium (mg);
(*8*) Total carbohydrate (g);
(*9*) Dietary fiber (g);
(*10*) Sugars (g); and
(*11*) Protein (g).

(B) If a standard menu item contains insignificant amounts of all the nutrients required to be disclosed in paragraph (b)(2)(ii)(A) of this section, the establishment is not required to include nutrition information regarding the standard menu item in the written form. However, if the covered establishment makes a nutrient content claim or health claim, the establishment is required to provide nutrition information on the nutrient that is the subject of the claim in accordance with § 101.10. For standard menu items that contain insignificant amounts of six or more of the required nutrients, the declaration of nutrition information required by paragraph (b)(2)(ii)(A) of this section may be presented in a simplified format.

(*1*) An insignificant amount is defined as that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrates, dietary fiber, and protein, it must be an amount that allows a declaration of ''less than one gram.''

(*2*) The simplified format must include information, in a column, list, or table, on the following nutrients:

(*i*) Total calories, total fat, total carbohydrates, protein, and sodium; and

(*ii*) Calories from fat, and any other nutrients identified in paragraph (b)(2)(ii)(A) of this section that are present in more than insignificant amounts.

(*3*) If the simplified format is used, the statement ''Not a significant source of ____'' (with the blank filled in with the names of the nutrients required to be declared in the written nutrient information and calories from fat that are present in insignificant amounts) must be included at the bottom of the list of nutrients.

(C) For variable menu items, the nutrition information listed in paragraph (b)(2)(ii)(A) of this section must be declared as follows for each size offered for sale:

(*1*) The nutrition information required in paragraph (b)(2)(ii)(A) of this section

must be declared for the basic preparation of the item and, separately, for each topping, flavor, or variable component.

(*2*) Additional format requirements for toppings if the amount of the topping included on the basic preparation of the menu item decreases based on the total number of toppings ordered for the menu item (such as is sometimes the case with pizza toppings). The nutrients for such topping must be declared as single values representing the nutrients for each topping when added to a one-topping menu item, specifying that the nutrient declaration is for the topping when added to a one-topping menu item.

(*3*) If the calories and other nutrients are the same for different flavors, varieties, and variable components of the combination meal, each variety, flavor, and variable component of the combination meal is not required to be listed separately. All items that have the same nutrient values could be listed together with the nutrient values listed only once.

(D) The written nutrition information required in paragraph (b)(2)(ii)(A) of this section may be provided on a counter card, sign, poster, handout, booklet, loose leaf binder, or electronic device such as a computer, or in a menu, or in any other form that similarly permits the written declaration of the required nutrient content information for all standard menu items. If the written nutrition information is not in a form that can be given to the customer upon request, it must be readily available in a manner and location on the premises that allows the customer/consumer to review the written nutrition information upon request.

(iii) The following must be provided for a standard menu item that is self-service or on display.

(A) Calories per displayed food item (*e.g.,* a bagel, a slice of pizza, or a muffin), or if the food is not offered for sale in a discrete unit, calories per serving (*e.g.,* scoop, cup), and the serving or discrete unit used to determine the calorie content (*e.g.,* ''per scoop'' or ''per muffin'') on either: A sign adjacent to and clearly associated with the corresponding food; (*e.g.,* ''150 calories per scoop''); a sign attached to a sneeze guard with the calorie declaration and the serving or unit used to determine the calorie content above each specific food so that the consumer can clearly associate the calorie declaration with the food, except that if it is not clear to which food the calorie declaration and serving or unit refers, then the sign must also include the name of the food, *e.g.,* ''Broccoli and cheese casserole—200 calories per scoop''; or a single sign or placard listing the calorie declaration for several food items along with the names of the food items, so long as the sign or placard is located where a consumer can view the name, calorie declaration, and serving or unit of a particular item while selecting that item.

(*1*) For purposes of paragraph (b)(2)(iii)(A) of this section, ''per displayed food item'' means per each discrete unit offered for sale, for example, a bagel, a slice of pizza, or a muffin.

(*2*) For purposes of paragraph (b)(2)(iii)(A) of this section, ''per serving'' means, for each food:

(*i*) Per serving instrument used to dispense the food offered for sale, provided that the serving instrument dispenses a uniform amount of the food (*e.g.,* a scoop or ladle);

(*ii*) If a serving instrument that dispenses a uniform amount of food is not used to dispense the food, per each common household measure (*e.g.,* cup or tablespoon) offered for sale or per unit of weight offered for sale, *e.g.,* per quarter pound or per 4 ounces; or

(*iii*) Per total number of fluid ounces in the cup in which a self-service beverage is served and, if applicable, the description of the cup size (*e.g.,* ''140 calories per 12 fluid ounces (small)'').

(*3*) The calories must be declared in the following manner:

(*i*) To the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories except that amounts less than 5 calories may be expressed as zero.

(*ii*) If the calorie declaration is provided on a sign with the food's name, price, or both, the calorie declaration, accompanied by the term ''Calories'' or ''Cal'' and the amount of the serving or displayed food item on which the calories declaration is based must be in a type size no smaller than the type size of the name or price of the menu item whichever is smaller, in the same color, or a color that is at least as conspicuous as that used for that name or price, using the same contrasting background or a background at least as contrasting as that used for that name or price. If the calorie declaration is provided on a sign that does not include the food's name, price, or both, the calorie declaration, accompanied by the term ''Calories'' or ''Cal'' and the amount of the serving or displayed food item on which the calorie declaration is based must be clear and conspicuous.

(*iii*) For self-service beverages, calorie declarations must be accompanied by the term ''fluid ounces'' and, if applicable, the description of the cup size (*e.g.,* ''small,'' ''medium'').

(B) For food that is self-service or on display and is identified by an individual sign adjacent to the food itself where such sign meets the definition of a menu or menu board under paragraph (a) of this section, the statement required by paragraph (b)(2)(i)(B) of this section and the statement required by paragraph (b)(2)(i)(C) of this section. These two statements may appear on the sign adjacent to the food itself; on a separate, larger sign, in close proximity to the food that can be easily read as the consumer is making order selections; or on a large menu board that can be easily read as the consumer is viewing the food.

(C) The nutrition information in written form required by paragraph (b)(2)(ii) of this section, except for packaged food insofar as it bears nutrition labeling information required by and in accordance with paragraph (b)(2)(ii) of this section and the packaged food, including its label, can be examined by a consumer before purchasing the food.

(c) *Determination of nutrient content.* (1) A covered establishment must have a reasonable basis for its nutrient declarations. Nutrient values may be determined by using nutrient databases (with or without computer software programs), cookbooks, laboratory analyses, or other reasonable means, including the use of Nutrition Facts on labels on packaged foods that comply with the nutrition labeling requirements of section 403(q)(1) of the Federal Food, Drug, and Cosmetic Act and § 101.9, FDA nutrient values for raw fruits and vegetables in Appendix C of this part, or FDA nutrient values for cooked fish in Appendix D of this part.

(2) Nutrient declarations for standard menu items must be accurate and consistent with the specific basis used to determine nutrient values. A covered establishment must take reasonable steps to ensure that the method of preparation (*e.g.,* types and amounts of ingredients, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(3) A covered establishment must provide to FDA, within a reasonable period of time upon request, information substantiating nutrient values including the method and data used to derive these nutrient values. This information must include the following:

(i) For nutrient databases:

(A) The name and version (including the date of the version) of the database,

and, as applicable, the name of the applicable software company and any Web site address for the database. The name and version of a database would include the name and version of the computer software, if applicable;

(B) The recipe or formula used as a basis for the nutrient declarations;

(C)(*1*) Information on:

(*i*) The amount of each nutrient that the specified amount of each ingredient identified in the recipe contributes to the menu item; and

(*ii*) How the database was used including calculations or operations (*e.g.,* worksheets or computer printouts) to determine the nutrient values for the standard menu items;

(*2*) If the information in paragraph (c)(3)(i)(C)(*1*) of this section is not available, certification attesting that the database will provide accurate results when used appropriately and that the database was used in accordance with its instructions;

(D) A detailed listing (*e.g.,* printout) of the nutrient values determined for each standard menu item.

(E) Any other information pertinent to the final nutrient values of the standard menu item (*e.g.,* information about what might cause slight variations in the nutrient profile such as moisture variations);

(F) A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and

(G) A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.,* types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(ii) For published cookbooks that contain nutritional information for recipes in the cookbook:

(A) The name, author, and publisher of the cookbook used;

(B) If available, information provided by the cookbook or from the author or publisher about how the nutrition information for the recipes was obtained;

(C) A copy of the recipe used to prepare the standard menu item and a copy of the nutrition information for that standard menu item as provided by the cookbook; and

(D) A statement signed and dated by a responsible individual employed at the covered establishment certifying that that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.,* types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined. (Recipes may be divided as necessary to accommodate differences in the portion size derived from the recipe and that are served as the standard menu item but no changes may be made to the proportion of ingredients used.)

(iii) For laboratory analyses:

(A) A copy of the recipe for the standard menu item used for the nutrient analysis;

(B) The name and address of the laboratory performing the analysis;

(C) Copies of analytical worksheets, including the analytical method, used to determine and verify nutrition information;

(D) A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and

(E) A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.*, types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(iv) For nutrition information provided by other reasonable means:

(A) A detailed description of the means used to determine the nutrition information;

(B) A recipe or formula used as a basis for the nutrient determination;

(C) Any data derived in determining the nutrient values for the standard menu item, *e.g.*, nutrition information about the ingredients used with the source of the nutrient information;

(D) A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and

(E) A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.*, types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(d) *Voluntary registration to be subject to the menu labeling requirements*—(1) *Applicability.* A restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items may voluntarily register to be subject to the requirements established in this section. Restaurants and similar retail food establishments that voluntarily register will no longer be subject to non-identical State or local nutrition labeling requirements.

(2) *Who may register?* The authorized official of a restaurant or similar retail food establishment as defined in paragraph (a) of this section, which is not otherwise subject to paragraph (b) of this section, may register with FDA.

(3) *What information is required?* Authorized officials for restaurants and similar retail food establishments must provide FDA with the following information on Form FDA 3757:

(i) The contact information (including name, address, phone number, and email address) for the authorized official;

(ii) The contact information (including name, address, phone number, and email address) of each restaurant or similar retail food establishment being registered, as well as the name and contact information for an official onsite, such as the owner or manager, for each specific restaurant or similar retail food establishment;

(iii) All trade names the restaurant or similar retail food establishment uses;

(iv) Preferred mailing address (if different from location address for each establishment) for purposes of receiving correspondence; and

(v) Certification that the information submitted is true and accurate, that the person submitting it is authorized to do so, and that each registered restaurant or similar retail food establishment will be subject to the requirements of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act and this section.

(4) *How to register.* Authorized officials of restaurants and similar retail food establishments who elect to be subject to requirements in section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act can register by visiting *http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm217762.htm.* FDA has created a form (Form 3757) that contains fields requesting the information in paragraph (d)(3) of this section and made the form available at

this Web site. Registrants must use this form to ensure that complete information is submitted.

(i) Information should be submitted by email by typing complete information into the form (PDF), saving it on the registrant's computer, and sending it by email to *menulawregistration@fda.hhs.gov.*

(ii) If email is not available, the registrant can either fill in the form (PDF) and print it out (or print out the blank PDF and fill in the information by hand or typewriter), and either fax the completed form to 301–436–2804 or mail it to FDA, CFSAN Menu and Vending Machine Registration, White Oak Building 22, Rm. 0209, 10903 New Hampshire Ave., Silver Spring, MD 20993.

(5) *When to renew the registration.* To keep the establishment's registration active, the authorized official of the restaurant or similar retail food establishment must register every other year within 60 days prior to the expiration of the establishment's current registration with FDA. Registration will automatically expire if not renewed.

(e) *Signatures.* Signatures obtained under paragraph (d) of this section that meet the definition of electronic signatures in § 11.3(b)(7) of this chapter are exempt from the requirements of part 11 of this chapter.

(f) *Misbranding.* A standard menu item offered for sale in a covered establishment shall be deemed misbranded under sections 201(n), 403(a), 403(f) and/or 403(q) of the Federal Food, Drug, and Cosmetic Act if its label or labeling is not in conformity with paragraph (b) or (c) of this section.

Dated: November 19, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27833 Filed 11–25–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

[Docket No. FDA–2011–F–0171]

RIN 0910–AG56

Food Labeling; Calorie Labeling of Articles of Food in Vending Machines

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: To implement the vending machine food labeling provisions of the Patient Protection and Affordable Care Act of 2010 (ACA), the Food and Drug Administration (FDA or we) is establishing requirements for providing calorie declarations for food sold from certain vending machines. This final rule will ensure that calorie information is available for certain food sold from a vending machine that does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article, or does not otherwise provide visible nutrition information at the point of purchase. The declaration of accurate and clear calorie information for food sold from vending machines will make calorie information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices. This final rule applies to certain food from vending machines operated by a person engaged in the business of owning or operating 20 or more vending machines. Vending machine operators not subject to the rules may elect to be subject to the Federal requirements by registering with FDA.

DATES:

Effective Date: December 1, 2016.

Compliance Date: Covered vending machine operators must comply with the rule by December 1, 2016. See section III.E for more information on the effective and compliance dates.

Comment Date: Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by December 31, 2014 (see section V, the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: To ensure that comments on the information collection are received, the Office of Management and Budget (OMB) recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910—New and title ''Information Collection Provisions of the final rule on Food Labeling: Calorie Labeling of Articles of Food in Vending Machines.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Y. Reese, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371, email: *Daniel.Reese@fda.hhs.gov.*

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Executive Summary

Purpose and Coverage of the Final Rule

To help make calorie information for vending machine foods available to prospective purchasers in a direct, accessible, and consistent manner to enable them to make informed and healthful dietary choices, section 4205 of the ACA and the rule require that vending machine operators who own or operate 20 or more vending machines, or who voluntarily elect to be covered, must provide calorie declarations for those vending machine foods for which the Nutrition Facts label cannot be examined prior to purchase or for which visible nutrition information is not otherwise provided at the point of purchase.

Summary of the Major Provisions of the Final Rule

- The final rule requires vending machine operators who own or operate 20 or more vending machines (or who voluntarily register with FDA to be subject to the final rule) to provide calorie declarations for certain articles of food sold from vending machines.
  - The final rule defines a vending machine operator as a person or entity that controls or directs the function of the vending machine, including deciding which articles of food are sold from the machine or the placement of the articles of food within the vending machine, and is compensated for the control or direction of the function of the vending machine.
  - Through biannual registration, vending machine operators who are not covered by the final rule can voluntarily elect to become subject to it.
- The final rule describes which foods are subject to the calorie

declaration requirement. Vending machine operators do not have to declare calorie information for a food if a prospective purchaser can view certain calorie information on the front of the package, in the Nutrition Facts label on the food, or in a reproduction of the Nutrition Facts label on the food subject to certain requirements, or if the vending machine operator does not own or operate 20 or more vending machines.

- For those foods subject to the calorie declaration requirement, the final rule specifies how the calories must be declared.

○ Calorie declarations must be clear and conspicuous and placed prominently, and may be placed on a sign in, on, or adjacent to the vending machine, so long as the sign is in close proximity to the article of food or selection button.

○ The final rule establishes type size, color, and contrast requirements for calorie declarations in or on the vending machines, and for calorie declarations on signs adjacent to the vending machines.

○ The final rule establishes requirements for calorie declarations on electronic vending machines, those vending machines with only pictures or names of the food items, and those vending machines with few choices (*e.g.,* popcorn machines).

- The final rule requires vending machine operator contact information to be displayed for enforcement purposes.

- The final rule makes conforming amendments to FDA's labeling regulations at § 101.9(j) so that a covered vending machine food that is otherwise exempt from nutrition labeling under § 101.9 would not lose such exemption by complying with the calorie declaration requirements of the final rule.

Costs and Benefits

The Affordable Care Act requires nutrition labeling for standard menu items on menus and menu boards for certain restaurants and similar retail food establishments and calorie labeling for food sold from certain vending machines. FDA is issuing two separate final rules (one for menu labeling and one for vending machine labeling) to implement those labeling requirements. For this rule on vending machines alone, the expected annualized costs are $37.9 million (over 20 years discounted at 7 percent), while the benefits have not been quantified. Taken together, the mean estimated benefits of the labeling requirements (menu labeling and vending machine labeling rules combined) exceed costs by $477.9 million on an annualized basis (over 20 years discounted at 7 percent; not including net benefits from this final rule on vending machine labeling, which are not quantified).

SUMMARY OF COSTS AND BENEFITS OF MENU LABELING AND VENDING MACHINE RULES (IN MILLIONS) *

	Rate percent)	Benefits	Costs	Net benefits
Total for Labeling (menu and vending rules) over 20 years	3	$9,221.3	$1,697.9	$7,523.4
	7	6,752.8	1,333.9	5,418.9
Annualized for Labeling (menu and vending rules) over 20 years	3	$601.9	$110.8	491.1
	7	595.5	117.6	477.9
Total for Vending Machine Labeling over 20 years	3	Not Quantified	531.1	
	7	Not Quantified	401.1	
Annualized for Vending Machine Labeling over 20 years	3	Not Quantified	34.7	
	7	Not Quantified	35.4	

* Benefits from this vending machine labeling rule are not quantified and therefore not included.

I. Background

The Nutrition Labeling and Education Act of 1990 (NLEA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to require, in part, nutrition information for food labeling (section 403(q) (21 U.S.C. 343(q)). Under the NLEA and its implementing regulations (§ 101.9 (21 CFR 101.9)), when a food is in package form, the required nutrition information generally must appear on the label of the food. The regulations require nutrition information to be provided for a food product intended for human consumption and offered for sale unless an exemption applies (§ 101.9(a)). One of these exemptions applied to food products served in a vending machine, provided that the food bore no nutrition claims or other nutrition information in any context on the label or in the labeling or advertising (§ 101.9(j)(2)).

On March 23, 2010, the President signed the ACA (Public Law 111–148) into law. Section 4205 of the ACA amended section 403(q) of the FD&C Act and section 403A of the FD&C Act (21 U.S.C. 343–1), which governs Federal preemption of State and local food labeling requirements. Section 4205 of the ACA added section 403(q)(5)(H)(viii) to the FD&C Act to require that if an article of food is sold from a vending machine that (1) ''does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase;'' and (2) ''is operated by a person who is engaged in the business of owning or operating 20 or more vending machines,'' then the vending machine operator must ''provide a sign in close proximity to each article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article.''

Under section 403(q)(5)(H)(ix) of the FD&C Act, vending machine operators who are not subject to the new requirements of section 403(q)(5)(H)(viii) of the FD&C Act can register voluntarily with FDA to become subject to the Federal requirements. In the **Federal Register** of July 23, 2010 (75 FR 43182), we published a notice specifying the terms and conditions for implementation of voluntary registration, pending issuance of regulations.

II. Legal Authority

Section 4205 of the ACA amended section 403(q)(5) of the FD&C Act, in part, by adding a new paragraph (H) to require certain vending machine operators to provide calorie declarations for certain articles of food sold from vending machines. Under section 403(a)(1) of the FD&C Act, such information must be truthful and non-misleading. Under section 403(f) of the FD&C Act, any word, statement, or other information required by or under the FD&C Act to appear on the label or labeling of an article of food must be prominently placed thereon with such conspicuousness (as compared with

other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Food to which these requirements apply is deemed misbranded if these requirements are not met. In addition, under section 201(n) of the FD&C Act (21 U.S.C. 321(n)), the labeling of food is misleading if it fails to reveal facts that are material in light of representations made in the labeling or with respect to consequences that may result from use. Thus, we are issuing this final rule under sections 201(n), 403(a)(1), 403(f), and 403(q)(5)(H) of the FD&C Act, as well as under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which gives us the authority to issue regulations for the efficient enforcement of the FD&C Act.

III. Comments on the Proposed Rule, FDA Responses, and Description of the Final Rule

A. Introduction

In the **Federal Register** of April 6, 2011 (76 FR 19238), we published a proposed rule that would establish requirements for calorie declarations for certain articles of food sold from vending machines to implement section 403(q)(5)(H)(viii) and (q)(5)(H)(ix) of the FD&C Act. We proposed definitions, requirements for calorie labeling for certain food sold from vending machines, and requirements for voluntary registration by a vending machine operator that is not subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act to elect to be subject to such requirements. We provided a 90-day comment period that ended on July 5, 2011.

We received approximately 250 comments on the proposed rule each containing one or more issues. We received comments from consumers; consumer groups; trade organizations; the vending machine industry; public health organizations; Congress; Federal, State, and local government agencies; and other organizations.

We describe and respond to the comments in sections III.B, C, D, and E of this document. To make it easier to identify comments and our responses, the word ''Comment,'' in parentheses, will appear before the comment's description, and the word ''Response,'' in parentheses, will appear before our response. We have also numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

B. General Comments

Many comments made general remarks supporting or opposing the rule and did not focus on a particular section of the rule. Other comments addressed FDA's statutory interpretations and general economic issues. We address the general comments including general comments relating to FDA's statutory interpretations and general economic issues here.

(Comment 1) The majority of comments supported the proposed rule. Some comments stated that the proposed rule strikes the right balance between making important nutrition information available to consumers and avoiding unnecessary financial burdens on small businesses. Other comments said requiring vending machines to display calorie information is an integral part of a comprehensive approach to addressing obesity by providing consumers with more information to make healthier choices. Some comments supported the proposed rule's flexibility regarding how covered operators are to declare calories on signs.

In contrast, other comments opposed the proposed rule. Some comments stated that people do not need to be told what to eat. One comment stated that labeling responsibilities should be placed on food manufacturers, rather than vending machine operators, because food manufacturers already have the information and can place it on the food label. One comment asserted that calorie declarations on signs in close proximity to articles of food sold in vending machines or selections buttons are unnecessary because packaged foods already have nutrition information on the labels for such foods.

(Response 1) The final rule does not attempt to tell consumers what they should or should not eat. The final rule requires certain vending machine operators to provide calorie declarations for certain articles of food sold from vending machines on signs in close proximity to such articles of food or selection buttons as required by section 403(q)(5)(H)(viii) of the FD&C Act. The purpose of the final rule is to provide accurate and clear calorie information for vending machine foods to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices.

As for the comment stating that food manufacturers rather than vending machine operators should be responsible for providing calorie declarations for vending machine foods, section 403(q)(5)(H)(viii) of the FD&C Act expressly applies to certain vending machine operators. Therefore, we decline to revise the rule to apply the requirements of section 403(q)(5)(H)(viii) of the FD&C Act to food manufacturers.

We note that some packaged foods may already list nutrition information (including calories) on their labels. Such articles of food may be exempt from the requirements of section 403(q)(5)(H)(viii) of the FD&C Act if they satisfy the criteria set forth in § 101.8(b).

(Comment 2) Some comments opposed the proposed rule, stating that the costs and work to implement the proposed requirements would be better spent on other programs. Other comments questioned the value of the calorie declaration requirements and asserted that the proposed rule would increase the cost of packaged foods sold in vending machines. Another comment suggested that the Federal Government provide tax incentives to small businesses to offset costs of implementing the rule.

Other comments questioned whether disclosing calorie information would have the intended benefits. The comments questioned whether vending machine calorie labeling would promote healthier choices and the need to educate consumers about the calorie information. The comments also questioned whether consumers would ignore the calorie information, and whether the calorie information would affect consumer behavior.

(Response 2) With respect to those comments suggesting that Federal funds and labor would be better spent on other matters, section 4205 of the ACA requires us to issue regulations to implement the vending machine labeling requirements, as specified in section 403(q)(5)(H)(viii) of the FD&C Act.

The final rule does not require food manufacturers to change the labeling of packaged foods, nor does it require vending machine manufacturers to change the design of vending machines. Nevertheless, it is possible that some costs associated with compliance with this rulemaking might pass through to consumers. However, any changes to the cost of packaged foods sold in vending machines are likely to be very small, because the estimated costs of compliance would be very small relative to overall sales from vending machines. The final rule is directed at certain vending machine operators, and we discuss the final rule's economic impact and its impact on small businesses in a

full Regulatory Impact Analysis for the final rule (Ref. 1) which is available at *http://www.regulations.gov* (enter Docket No. FDA–2011–F–0171).

As for the comments suggesting tax incentives for small businesses, we recognize that nearly 97 percent of the covered vending machine operators are small businesses, and have provided flexibility in the final rule to reduce the burden on small businesses. Specifically, we have changed the final rule's effective date from 1 year to 2 years, and are allowing covered vending machine operators to choose the method for determining calorie content of the food and the materials through which the calories are declared, including less expensive means such as stickers or signs. We believe this additional flexibility will help minimize burdens on and costs for small businesses in complying with the requirements of section 403(q)(5)(H)(viii) of the FD&C Act.

With respect to the comments questioning the rule's potential benefits, we note that section 4205 of the ACA requires FDA to implement the calorie labeling requirements for vending machines in section 403(q)(5)(H)(viii) of the FD&C Act. Further, the declaration of accurate and clear calorie information for food sold from vending machines will make calorie information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices.

(Comment 3) The vending machine labeling requirements in section 403(q)(5)(H)(viii) of the FD&C Act apply to all covered food sold from vending machines operated by a person who is engaged in the business of owning or operating 20 or more vending machines. The preamble to the proposed rule indicates that, as with other vending machine operators, vending machine operators who are blind and operate vending machines through the Vending Facility Program of the Randolph-Sheppard Act of 1936, 20 U.S.C. 107 *et seq.,* would be covered by the requirements of section 403(q)(5)(H)(viii) of the FD&C Act only if they operate 20 or more vending machines that dispense food or if they voluntarily register to be covered (76 FR 19238 at 19240–19241).

Several comments asked that we retain the explanation from the preamble to the proposed rule that section 403(q)(5)(H)(viii) of the FD&C Act does not apply to vending machine operators who are blind and operate vending machines through the Vending Facility Program of the Randolph-Sheppard Act if they operate fewer than 20 machines. The comments expressed concern that, because State licensing agencies responsible for administering the Randolph-Sheppard Act often own the vending machines, vending machine operators would be subject to the calorie declaration requirements even if they operate fewer than 20 machines.

(Response 3) Section 403(q)(5)(H)(viii) of the FD&C Act applies to all covered food sold from vending machines ''operated by a person who is engaged in the business of owning or operating 20 or more vending machines.'' Thus, if a vending machine operator under the Vending Facility Program of the Randolph-Sheppard Act does not own or operate 20 or more vending machines, then the food sold from his or her vending machines is outside the scope of the final rule unless the vending machine operator voluntarily registers to be covered by the rule under § 101.8(d).

(Comment 4) One comment asked that we clarify that vending machine operators, rather than food manufacturers, must comply with this final rule.

(Response 4) Section 403(q)(5)(H)(viii) of the FD&C Act makes it clear that the requirements apply to vending machine operators rather than food manufacturers.

Nevertheless, a food manufacturer may provide the number of calories for a vending machine food to a vending machine operator to help the vending machine operator meet the calorie declaration requirements of this rule. In addition, the label for a vending machine food may already include calorie information, which the vending machine operator may use in providing the calorie declarations required by this rule. Further, as food packaging and vending machine technology continue to evolve, food manufacturers, vending machine manufacturers, and vending machine operators may work together to help vending machine operators comply with this rule.

(Comment 5) One comment asked whether dietary supplements and over-the-counter drugs (*e.g.,* cough drops), which are sometimes sold in vending machines, would be covered by the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. The comment noted that, in some cases, these products bear calorie information, but the information is within the context of the Drug or Supplement Facts, and not on the front of package (FOP). The comment stated that dietary supplements and over-the-counter drugs should not be considered articles of food and that we should not apply the calorie labeling requirements to these types of items.

(Response 5) Section 201(f) of the FD&C Act defines ''food'' as: ''(1) Articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.'' Further, section 201(ff) of the FD&C Act explains that dietary supplements are deemed to be foods within the meaning of the FD&C Act except for the purposes of sections 201(g) (definition of ''drug'') and 417 (21 U.S.C. 350f) (reportable food registry) of the FD&C Act. The requirements of section 403(q)(5)(H)(viii) of the FD&C Act apply ''[i]n the case of an article of food sold from a vending machine'' and, therefore, apply to dietary supplements, but do not apply to drugs, including over-the-counter drugs.

(Comment 6) Some comments requested that foods in small packages whose total surface area available to bear labeling is less than 12 square inches, *e.g.,* gum and mints, be exempted from the rule; these comments said such an exemption would be consistent with the existing exemption from nutrition labeling for foods in small packages (§ 101.9(j)(13)). One comment further reasoned that an exemption for foods sold in small packages would be appropriate because such packaged foods lack sufficient label space to provide FOP calorie information that would be easily readable by the consumer through the vending machine window. The comment also speculated that vending machine operators may no longer choose to sell gums and mints in most vending machines. Some comments also noted that these foods in small packages provide an insignificant calorie contribution to the daily diet and requested that such foods be exempted from this rule. These comments argued that the burden of providing calorie information is not justified for such foods.

Some comments stated that foods exempt from nutrition labeling under § 101.9(j) would lose this exemption if they must bear calorie information on the front of the package. Similarly, other comments asked us to exempt bottled water from this rule because bottled water contains insignificant amounts of nutrients and is generally exempt from the nutrition labeling requirements of § 101.9 under the exemption for packaged foods in § 101.9(j)(4). One comment expressed concern that, if bottled water products must comply with this rule, the bottled water would be required to have a Nutrition Facts Panel even though it may be otherwise exempt from the nutrition labeling requirements. The comment expressed concern that vending machine operators

may stock less bottled water because they would stock products only with nutrition information on the label or FOP labeling so that they would not have to post calorie declarations themselves.

(Response 6) The comments referring to the exemptions are describing § 101.9(j)(4) and (j)(13)(i), which FDA issued to implement section 403(q)(5)(B) and (C) of the FD&C Act before the enactment of the ACA. Section 101.9(j)(13)(i) provides that foods in small packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from the nutrition labeling requirements of § 101.9 provided that the labels for these foods bear no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. In addition, § 101.9(j)(4) provides in relevant part that foods containing insignificant amounts of all of the nutrients and food components required to be included in the declaration of nutrition information under § 101.9(c) are exempt from the nutrition labeling requirements of § 101.9 provided that these foods bear no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. However, these exemptions only apply to the requirements of section 403(q)(1) and (2) of the FD&C Act, and not the vending machine labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act.

Also, section 403(q)(5)(H)(viii) of the FD&C Act does not include an exemption for vending machine foods based on the package size, amount of nutrients, or caloric content of such foods. Instead, it provides that calorie declarations are not required for food sold from a vending machine: (1) That permits a prospective purchaser to examine the Nutrition Facts Panel before purchasing the food; or (2) that otherwise provides visible nutrition information at the point of purchase. If a vending machine food does not fall into either of these two categories, a covered vending machine operator must provide calorie information for the food.

We note that this final rule requires a covered vending machine operator to post calorie information on a sign in close proximity to a vending machine food or its selection button; it does not require that such calorie information be included on the label of a vending machine food. Further, the final rule provides a number of options for covered vending machine operators to post the required calorie information, including posting such information on a sign adjacent to a vending machine (§ 101.8(c)(2)). As a result, the practical limitations that may apply to including nutrition information on the labels of foods in small packages do not apply to posting calorie information on signs for vending machine food. For these reasons, we are not exempting vending machine foods that come in small packages (*e.g.,* gum, mints) or vending machine foods that contain insignificant nutrient or caloric content (*e.g.,* bottled water) from the requirements of section 403(q)(5)(H)(viii) of the FD&C Act.

We are also making changes to clarify that a covered vending machine food that is exempt from nutrition labeling under an exemption provided in § 101.9(j) would not lose such exemption by complying with the final rule's calorie labeling requirements. As noted previously, § 101.9(j) provides exemptions from the requirements of § 101.9, including exemptions that apply to vending machine foods. Section 101.9(j)(2)(ii) provides, in relevant part, that food products which are served in establishments other than restaurants in which food is served for immediate human consumption, including vending machines, are exempt from the nutrition labeling requirements of § 101.9 provided that these foods bear no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Similarly, § 101.9(j)(4) and (j)(13)(i) provide exemptions from the requirements of § 101.9 provided that the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Because of these provisions, a vending machine food that complies with the final rule's calorie labeling requirements would not qualify for the exemptions from nutrition labeling in § 101.9(j)(2)(ii), (j)(4), and (j)(13)(i) because the labeling for such food would bear nutrition information.

To prevent this outcome, we have amended § 101.9(j) so that a covered vending machine food that is otherwise exempt from nutrition labeling under § 101.9(j) would not lose such exemption by complying with the final rule's calorie labeling requirements. We have amended § 101.9(j)(2)(ii), (j)(4), and (j)(13)(i) to clarify that complying with the vending machine food labeling requirements of § 101.8(c) will not cause a food product meeting the exemption to lose the exemption.

However, we note that providing visible nutrition information on the label of a vending machine food through FOP labeling would constitute a nutrient content claim under section 403(r) of the FD&C Act. Section 101.13 (21 CFR 101.13), which provides general principles for nutrient content claims, states, in relevant part, that information that is required or permitted by § 101.9 or § 101.36 (21 CFR 101.36), as applicable, to be declared in nutrition labeling, and that appears as part of the nutrition label, is not considered to be a nutrient content claim and is not subject to the requirements of this section, unless such information is declared elsewhere on the label or in labeling for the food (§ 101.13(c)). If nutrition information that is required or permitted by § 101.9 or § 101.36, including calorie information, appears some place other than the nutrition label for a food, such as on the front of the food's package, it is a nutrient content claim and is subject to the requirements for nutrient content claims (§ 101.13(c); 136 Cong. Rec. 20369, at 20419 (1990) (''Section 403(r)(1) has been amended to make it clear that the information on the nutrition label is not a claim under that provision and therefore is not subject to the disclosure requirements in section 403(r)(2) . . . but the identical information will be subject to section 403(r)(2) if it is included in a statement in another portion of the label.'')). Accordingly, visible nutrition information provided through FOP labeling would be considered a nutrient content claim because it is nutrition information that is ''declared elsewhere on the label'' for a food. As such, a covered vending machine food that provides visible nutrition information at the point of purchase through FOP labeling would not qualify for the exemptions from nutrition labeling in § 101.9(j)(2)(ii), (j)(4), and (j)(13)(i), and therefore would be subject to the nutrition labeling requirements in § 101.9.

(Comment 7) One comment requested that we require vending machine operators to provide calorie declarations in a special format for visually impaired customers. The comment suggested that this format could be large font, Braille, or audio recordings.

(Response 7) We acknowledge the potential difficulty that visually impaired consumers may confront if the calorie declaration exists only in visual form, and we would not object if vending machine operators wish to develop means, such as large font, Braille, or audio, to help provide calorie declarations to visually impaired consumers, so long as the vending machine operators otherwise satisfy the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. We also would not object if vending machine and food manufacturers and designers decide to consider the needs of visually impaired consumers when manufacturing and designing their

products. However, we are not requiring vending machine operators to provide calorie declarations in a special format for visually impaired consumers at this time.

(Comment 8) A few comments supporting the proposed rule noted that requiring calorie labeling for vending machine foods sold in schools would be beneficial. These comments noted that vending machines typically are located in schools. Some of these comments asked that we require covered vending machine operators to provide separate calorie information for children, or list appropriate ''daily calorie ranges or percentages'' for children.

(Response 8) We agree that calorie labeling for vending machine foods, including vending machine foods sold in schools, would be beneficial.

Nevertheless, at this time, we decline to require covered vending machine operators to provide separate calorie information for children, or list appropriate ''daily calorie ranges or percentages'' for children as requested by some of the comments. Section 403(q)(5)(H)(viii) of the FD&C Act requires covered vending machine operators to provide a sign ''disclosing the number of calories contained in the [covered vending machine food].'' The number of calories contained in an article of food does not differ based on the population targeted or served by a vending machine.

Vending machine operators may voluntarily provide additional information that puts the calorie declaration for a covered vending machine food in the context of a total daily diet, provided that such information is truthful and not misleading. However, we decline to require such additional information in the final rule because we are only establishing regulations for the requirements of section 403(q)(5)(H)(viii) of the FD&C Act, and certain related provisions of section 403 of the FD&C Act, as described in section II, at this time.

(Comment 9) Some comments addressed issues unrelated to the proposed rule's specific calorie labeling requirements for covered vending machine food. These comments addressed color-coded package labeling, labeling genetically engineered foods, and labeling or highlighting other ingredients or nutrients (such as *trans* fat).

(Response 9) This rulemaking is intended to implement the vending machine calorie labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act. Thus, the issues raised by the comments are beyond the scope of this rulemaking.

(Comment 10) Some comments stated that FDA should not require covered vending machine operators to provide FOP calorie labeling or calorie declarations on signs in languages other than English, even if the label on the article of food is bilingual, but should allow the food manufacturer or distributor to voluntarily provide FOP calorie labeling or calorie declarations in a second language. One comment asked us to confirm that ''Cal'' is an acceptable abbreviation for ''Calories'' in both French and Spanish.

(Response 10) We are not requiring covered vending machine operators to provide calorie declarations for covered vending machine food in languages other than English, even if the label on the article of food is bilingual. FDA regulations at § 101.15(c)(1) (21 CFR 101.15(c)(1)) require that all words, statements, and other information required by the FD&C Act to appear on the label or labeling of food must appear in English, except that for foods distributed solely in Puerto Rico or other territories where the predominant language is not English, the predominant language may be substituted for English. Therefore, the calorie declarations provided by the covered vending machine operator, whether through the Nutrition Facts label or other visible nutrition information at the point of purchase (*e.g.,* FOP labeling) in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act or through a sign in close proximity to each article of food or the selection button in accordance with section 403(q)(5)(H)(viii) of the FD&C Act, must appear in English, unless the foods are distributed solely in Puerto Rico or other territories where the predominant language is not English, as provided in § 101.15(c)(1). In that context, we would consider ''Cal'' to be an acceptable abbreviation for ''Calories'' in French and Spanish.

C. Comments on Specific Provisions and Description of the Final Rule

Many comments addressed specific provisions in the proposed rule or related topics.

1. Section 11.1(h)—Electronic Signatures

Proposed § 11.1(h) would explain that part 11 (21 CFR part 11) regarding electronic signatures does not apply to electronic signatures obtained under the voluntary registration provision for vending machine operators at proposed § 101.8(d).

We received no comments on this provision and have finalized it without change.

2. Section 101.8(a)—Definitions

a. Use of statutory definitions. Proposed § 101.8(a) would define various terms. It also would explain that the definitions of terms in section 201 of the FD&C Act apply to such terms when used in proposed § 101.8. We received no comments regarding the use of statutory definitions in section 201 of the FD&C Act for the purposes of § 101.8, and we have finalized the sentence referring to the use of statutory definitions in § 101.8(a) without change.

b. ''Authorized Official of a Vending Machine Operator''. Proposed § 101.8(a) would define ''authorized official of a vending machine operator'' as the owner, operator, or agent in charge or any other person authorized by the vending machine operator to register the vending machine operator, which is not otherwise subject to the requirements of section 403(q)(5)(H) of the FD&C Act with FDA for purposes of proposed § 101.8(d). (Proposed § 101.8(d) would provide for voluntary calorie labeling for foods sold from vending machines.)

We received no comments regarding the proposed definition. However, on our own initiative, we have revised the definition to make non-substantive grammatical and technical changes (such as changing ''the vending machine operator'' to ''a vending machine operator'' and replacing ''FDA'' with ''the Food and Drug Administration''). We also have revised the definition to eliminate potential confusion as to who can be the authorized official of a vending machine operator by deleting an unnecessary conjunction (''or'') in the list of persons who may constitute an authorized official, to specify the provision of the FD&C Act covered by the final rule, and to move a descriptive phrase closer to the noun that it modifies. The final rule now defines an ''authorized official of a vending machine operator'' as an owner, operator, agent in charge, or any other person authorized by a vending machine operator who is not otherwise subject to section 403(q)(5)(H)(viii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)(viii)), to register the vending machine operator with the Food and Drug Administration ('FDA') for purposes of paragraph (d) of the section.

c. ''Vending Machine''. Proposed § 101.8(a) would define ''vending machine'' as a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses

servings of food in bulk or in packages, or prepared by the machine, without the necessity of replenishing the device between each vending operation.

(Comment 11) One comment argued that ''turret-style'' (also referred to as ''turnstile'') refrigerated vending machines do not meet the proposed definition of vending machine. According to the comment, once a food item in a turnstile vending machine is sold, the space that was occupied by the food becomes empty and needs to be restocked. The comment stated that a turnstile refrigerated vending machine, therefore, does not meet the part of the vending machine definition that reads: ''. . . without the necessity of replenishing the device between each vending operation.'' The comment also stated that the legislative intent of Congress may have been to exclude turnstile refrigerated vending machines, which are normally stocked with sandwiches, milk, burritos, or refrigerated foods because they are not the same as snack vending machines that primarily sell ''junk food.''

(Response 11) We disagree with the comment's assertion that ''turret-style'' or turnstile vending machines are outside the definition of ''vending machine.'' The definition uses the word ''replenished'' in relation to the ''device'' rather than the precise space the food once occupied. Contrary to the comment's interpretation, the final rule's definition of ''vending machine'' considers whether the machine, as a whole, needs to be restocked after each vending operation and not whether individual space(s) for food are ''replenished.''

If we were to accept the comment's interpretation and focus on the need to restock a specific space for a food after a vending operation, then one could argue that every vending machine would be outside the definition because operators do not necessarily restock each space after every purchase. It is true that, in turnstile vending machines, an empty space is created when a consumer buys an item from a particular space. However, the turnstile vending machine has multiple spaces within a level or tray, and the next consumer can rotate the turret to make another selection. Thus, the vending machine operator does not have to replenish the machine after each vending operation.

Furthermore, the type or nutritional quality of a food carried by the vending machine—whether it is a ''meal'' or a ''snack''—makes no difference under section 403(q)(5)(H)(viii) of the FD&C Act, nor did the proposed rule make such a distinction.

For these reasons, turret-style or turnstile vending machines are ''vending machines'' as defined by § 101.8(a). We note that the proposed definition used both the words ''device'' and ''machine'' interchangeably; for consistency, we have revised the definition of ''vending machine'' by replacing the term ''device'' with ''machine.''

d. ''Vending Machine Operator''. Proposed § 101.8(a) would define a ''vending machine operator'' as a person(s) or entity that controls or directs the function of the vending machine, including deciding which articles of food are sold from the machine or the placement of the articles of food within the vending machine, and is compensated for the control or direction of the function of the vending machine.

We received no comments on the proposed definition and have finalized it without change.

3. Section 101.8(b)—Articles of Food Not Covered

a. Ability to examine the nutrition facts label. Proposed § 101.8(b) would describe the circumstances under which articles of food dispensed from a vending machine are not ''covered vending machine food'' such that the requirements of section 403(q)(5)(H)(viii) of the FD&C Act do not apply. Proposed § 101.8(b)(1) would provide that an article of food dispensed from a vending machine is not ''covered vending machine food'' if the prospective purchaser ''can view the entire Nutrition Facts Panel on the label of the vended food without an obstruction,'' and the Nutrition Facts are the information, and are in the format, required in § 101.9(c) and (d), and in a size that ''permits the prospective purchaser to be able to easily read the nutrition information contained in the Nutrition Facts Panel on the label of the article of food in the vending machine.'' Proposed § 101.8(b)(1) also would provide that we would not consider the smaller formats allowed for Nutrition Facts for certain food labeling under § 101.9 to be a size that a prospective purchaser is able to easily read.

(Comment 12) Most comments supported proposed § 101.8(b)(1). One comment suggested that we give additional details as to how the food would need to be positioned in the vending machine in order to ensure the visibility of the Nutrition Facts Panel.

One comment objected to the proposed requirement that a prospective purchaser be able to view the entire Nutrition Facts Panel without an obstruction and said that would be too restrictive. The comment conceded that the dispensing coils in a vending machine might partially obscure the Nutrition Facts Panel, but said that each coil is only one-eighth of an inch wide, and virtually the entire Nutrition Facts Panel can be visible and readable in the vending machine making additional calorie disclosure unnecessary.

Another comment stated that we should not stipulate that modified or smaller formats of the Nutrition Facts Panel would not satisfy the requirements of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act. The comment said that it is possible that a product manufacturer or vending machine operator could design a clearly visible, readable, and conspicuous Nutrition Facts Panel in a modified or smaller format.

(Response 12) We are revising the rule as suggested by one comment. Section 101.8(b) of the final rule provides, in relevant part, that an article of food sold from a vending machine is not covered if the prospective purchaser can view the calories, serving size, and servings per container listed in the Nutrition Facts label (rather than ''the entire'' Nutrition Facts label) without any obstruction.

Under section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act, if the Nutrition Facts label on a vending machine food can be examined by a prospective purchaser before purchasing the article, a vending machine operator is not required to provide the calorie information required by section 403(q)(5)(H)(viii) of the FD&C Act for such food. (Although section 403(q)(5)(H)(viii) of the FD&C Act uses the term ''Nutrition Facts Panel'' and we used the same term in the proposed rule, for the purposes of this final rule, we use the term ''Nutrition Facts label'' instead of ''Nutrition Facts Panel'' to be consistent with how we generally refer to the nutrition information listed under the heading ''Nutrition Facts'' on the food label.)

In order for a consumer to examine the Nutrition Facts label to determine the amount of calories contained in the article of food, the consumer must be able to see the calories, serving size, and servings per container listed in the Nutrition Facts label. These pieces of information advance the overarching goal of the rule, which is to provide consumers with the necessary calorie information in a direct and accessible manner to enable consumers to make informed and healthful dietary choices. To conclude that the prospective purchaser must be able to see additional nutrition information on the Nutrition Facts label, beyond the number of calories contained in the article of food,

would mean that even if a prospective purchaser could see the relevant calorie information on the Nutrition Facts label, the vending machine operator would still be required to post a calorie declaration for the food under section 403(q)(5)(H)(viii) of the FD&C Act. Such a conclusion seems to provide a redundant or otherwise unnecessary outcome.

Therefore, we have revised § 101.8(b)(1) to indicate that the prospective purchaser must be able to view ''the calories, serving size, and servings per container listed in the Nutrition Facts label'' rather than ''the entire Nutrition Facts label'' itself. These three pieces of information must be visible ''without any obstruction.'' Regarding the comment suggesting that dispensing coils that are one-eighth of an inch thick should not be considered an obstruction, we disagree. Because there are different types of vending machines, different types of food products dispensed from vending machines, as well as different ways in which the Nutrition Facts label may be presented on a food package, any thickness of a coil could potentially obstruct one of the three required pieces of information.

Regarding the use of smaller formats of the Nutrition Facts label, as we noted in the preamble to the proposed rule (76 FR 19238 at 19243), it is unlikely that a prospective purchaser would be able to easily read the nutrition information prior to purchase, as required by section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act. We note that certain small format Nutrition Facts labels can display calories in as small as 6 point type size (see § 101.9(j)(13)(i)), and that the information in such formats is compressed (*e.g.,* linear or ''string'' format; see § 101.9(j)(13)(ii)(A)(2)). Because such formats are more difficult to read on vending machine foods prior to purchase, we, therefore, decline to consider a modified or smaller format size of the Nutrition Facts to be a size that a prospective purchaser could easily read prior to purchase. The comment did not provide any data or information (*e.g.,* label design) that would suggest that such a format would be readable.

On our own initiative, we have further revised § 101.8(b) to make certain non-substantive and editorial changes. We have replaced the term ''dispensed'' with ''sold'' in the first sentence in § 101.8(b) to better reflect the language of section 403(q)(5)(H)(viii) of the FD&C Act. We have moved the words ''the prospective purchaser'' in the first sentence of § 101.8(b)(1) to precede the colon that introduces § 101.8(b)(1) and (b)(2), inserted the words ''all the information in,'' in the first sentence of § 101.8(b)(1), deleted the words ''the information'' in the second sentence of § 101.8(b)(1), and replaced ''Nutrition Facts Panel'' with ''Nutrition Facts label'' in § 101.8(b)(1). We have also capitalized one instance of ''nutrition facts'' where it was not capitalized in the proposal and added the word ''or'' between § 101.8(b)(1) and (b)(2).

(Comment 13) Several comments asserted that any display (*e.g.,* a sign or electronic display) of the Nutrition Facts Panel should exempt the vending machine operator from the calorie declaration requirements. The comments added that a display would not have to be on the package of the vending machine food itself, but could be a reproduction of the Nutrition Facts Panel. Another comment stated that some electronic displays allow the consumer to view the full Nutrition Facts Panel and rotate a virtual image of the product, and that FDA should consider such displays sufficient in satisfying section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act.

(Response 13) We agree with the comments that certain reproductions of a Nutrition Facts label would be sufficient to satisfy section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act. Specifically, we conclude that a reproduction of a Nutrition Facts label that allows the prospective purchaser to view the calories, serving size, and servings per container would be sufficient to satisfy section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act if the reproduction is a reproduction of an actual Nutrition Facts label that complies with § 101.9 for a vending machine food, is presented in a size that permits the prospective purchaser to be able to easily read the nutrition information, and the calories, serving size, and servings per container are displayed by the vending machine before the prospective purchaser makes his or her purchase. Such reproductions could include electronic reproductions of the Nutrition Facts label displayed by a vending machine. Therefore, we have revised final § 101.8(b)(1) to allow for such reproductions of Nutrition Facts labels.

b. Visible nutrition information at the point of purchase. Proposed § 101.8(b)(2) would provide that an article of food dispensed from a vending machine is not covered vending machine food if the article provides ''visible nutrition information at the point of purchase,'' including the total number of calories for the article of food as dispensed.

Proposed § 101.8(b)(2) also would require that the visible nutrition information appear on the food label itself, and that it be ''clear and conspicuous and easily read on the article of food while in the vending machine, in a type size reasonably related to the largest printed matter on the label and with sufficient color and contrasting background to other print on the label to permit the prospective purchaser to clearly distinguish the information.''

(Comment 14) Because section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act and proposed § 101.8(b)(2) did not define the term ''visible nutrition information,'' the preamble to the proposed rule provided two possible interpretations for the term ''visible nutrition information'' (76 FR 19238 at 19244). We noted that one approach would be to conclude that ''nutrition information'' means ''total calories in the article of food.'' We noted that an alternative approach would be that ''nutrition information'' means ''something more than total calories'' and ''could include, in addition to total calories in the food, information such as serving size information or information on the nutrients that are required to be disclosed in the Nutrition Facts . . . .'' (Id.). The preamble to the proposed rule invited comment on ''what other nutrition information, if any, should be required if this alternative interpretation were adopted'' (Id.).

Many comments agreed that, in the context of the rule, the term ''nutrition information'' should mean total calories in the article of food. One comment pointed out that ''total calories'' is the information that section 403(q)(5)(H)(viii) of the FD&C Act otherwise requires covered vending machine operators to provide on a sign for foods sold in vending machines. Another comment would revise proposed § 101.8(b)(2) to read ''The visible nutrition information at the point of purchase may include *only* the total number of calories in the article of food, as dispensed, at the point of purchase'' (emphasis added).

Other comments supported the alternative approach, which interprets ''nutrition information'' as something more than total calories. These comments suggested that, for a vending machine food to be exempt from the requirements of section 403(q)(5)(H)(viii) of the FD&C Act, ''nutrition information'' should mean total calories as well as other information such as serving size information, the amount of other nutrients (*e.g.,* sodium, fat), and the presence of allergens. Another comment

stated that ''Congress did not depart from its previous definition of 'nutrition information' and as such it is logical to conclude that Congress intended the definition in [section] 343(q)(1) [of the FD&C Act] to apply to [section] 343(q)(5)(H)(viii)(I)(aa) [of the FD&C Act]—*i.e.,* the entire Nutrition Facts Panel or its equivalent be visible.''

(Response 14) As described previously, we noted in the proposed rule that there are two possible ways to interpret ''nutrition information'' within the meaning of section 403(q)(5)(H)(viii) of the FD&C Act. We noted that ''nutrition information'' could mean ''total calories in the article of food'' or ''something more than total calories'' (76 FR 19238 at 19244). As to any comments suggesting that our proposed interpretation that ''nutrition information'' means ''total calories'' is not a permissible interpretation, we conclude, as described in more detail to follow, that this interpretation is permissible in light of the language of section 403(q)(5)(H)(viii) of the FD&C Act and other sections of the FD&C Act.

The comments seem to be raising the question of what Congress intended ''nutrition information'' to mean within the context of section 403(q)(5)(H)(viii) of the FD&C Act. In construing section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented (''Chevron step one'')? *Chevron, U.S.A., Inc.* v. *NRDC, Inc.,* 467 U.S. 837, 842 (1984). If the ''intent of Congress is clear,'' an Agency ''must give effect to the unambiguously expressed intent of Congress.'' (Id. at 843.) However, if ''Congress has not directly addressed the precise question at issue,'' and the statute is ''silent or ambiguous with respect to the specific issue,'' then our interpretation of the term ''nutrition information'' will be upheld as long as it is based on a ''permissible construction'' of the statute (''Chevron step two''). *Chevron,* 467 U.S. at 842–43; *FDA* v. *Brown & Williamson Tobacco Corp,* 529 U.S. 120, 132 (2000). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue. See e.g., *Young* v. *Community Nutrition Institute,* 476 U.S. 974, 980 (1986).

We have determined that, in enacting section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act, Congress did not speak directly and precisely to the meaning of ''nutrition information.'' In conducting the Chevron step one analysis, all the traditional tools of statutory construction are available, *e.g.,* the statute's text, structure, and legislative history. *Pharmaceutical Research & Manufacturers of America* v. *Thompson,* 251 F.3d 219, 224 (D.C. Cir. 2001). Since the term is not defined in section 403(q)(5)(H)(viii) or elsewhere in the FD&C Act, we have examined the language and design of the FD&C Act as a whole to determine that the meaning of ''nutrition information'' in section 403(q)(5)(H)(viii) of the FD&C Act is ambiguous. See *e.g., Davis* v. *Michigan Department of Treasury,* 489 U.S. 803, 809 (1989) (''It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.''); *Martini* v. *Federal National Mortgage Association,* 178 F.3d 1336, 1345 (D.C. Cir. 1999). While the term ''nutrition information'' is used in other provisions of the FD&C Act, the term is typically accompanied by specific nutrients identified within the particular provision. For example, section 403(q)(1) of the FD&C Act provides that a food is misbranded unless its label or labeling bears certain nutrition information. Specifically, sections 403(q)(1)(C) to (E) of the FD&C Act identify particular nutrients included within the meaning of ''nutrition information'' under section 403(q)(1) of the FD&C Act (''A food shall be deemed misbranded . . . unless its label or labeling bears nutrition information that provides . . . the total number of calories . . . [t]otal fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein . . . any vitamin, mineral or other nutrient required to be placed on the label and labeling of food under this Act [under certain conditions].'').

Similarly, section 403(q)(5)(H)(ii)(III) of the FD&C Act, which was added to the FD&C Act by section 4205 of the ACA, along with the vending machine food labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act, explicitly requires restaurants and similar retail food establishments to provide ''the nutrition information required under clauses (C) and (D) of [section 403(q)(1) of the FD&C Act].'' Section 403(q)(5)(H)(viii) of the FD&C Act does not expressly identify nutrients other than the number of calories contained in a vending machine food. Further, as one comment noted, the number of calories contained in a vending machine food is the nutrition information that a vending machine operator must provide on a sign under section 403(q)(5)(H)(viii) of the FD&C Act if the provisions in section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act are not met. Having concluded that the meaning of ''nutrition information'' in section 403(q)(5)(H)(viii) of the FD&C Act is ambiguous, FDA has considered how to define the term so as to achieve a ''permissible construction'' (Chevron step two). *Chevron,* 467 U.S. at 842–43. In conducting the Chevron step two analysis, the same tools of statutory construction are available as those for the step one analysis. Because total calories is the nutrition information that a covered vending machine operator would otherwise have to provide on a sign for a covered vending machine food, we believe that ''nutrition information'' in the context of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act means, at a minimum, the number of calories contained in the vending machine food. To conclude that ''nutrition information'' means more than the total number of calories for an article of food would mean that even if a vending machine operator provided such calorie information on the label of the food, the operator would still be required to post a calorie declaration for the food under section 403(q)(5)(H)(viii) of the FD&C Act. Such a reading seems to provide a redundant or otherwise unnecessary outcome. For these reasons, we conclude that a vending machine that otherwise provides visible nutrition information at the point of purchase for an article of food must provide, at a minimum, the total calories in the vending machine food, in order for the requirements of section 403(q)(5)(H)(viii) of the FD&C Act to not apply to such food. As a result, we have revised § 101.8(b)(2) by inserting ''at a minimum'' before ''the total number of calories'' to specify that the label for a vending machine food may provide other nutrition information, including serving size information, in addition to the total number of calories.

In addition, we decline to amend § 101.8(b)(2) to include the phrase ''may include only'' the total number of calories in the vending machine food because it is not necessary to limit the information to calories. We would not object to food manufacturers or vending machine operators voluntarily providing information in addition to total calories to consumers at the point of purchase, provided that such information is truthful and not misleading and otherwise complies with the FD&C Act and FDA regulations.

On our own initiative, we have made non-substantive and editorial changes to § 101.8(b)(2) to complement the changes we made to § 101.8(b)(1), as described in our response to comment 8. We have revised the first sentence in § 101.8(b)(2) to state that the prospective purchaser can otherwise view visible nutrition information, including, at a minimum

the total number of calories for the article of food as sold at the point of purchase. We discuss additional considerations and changes to § 101.8(b)(2) in our response to comments 15 and 16 in the paragraphs that follow.

(Comment 15) Because section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act does not specify how a vending machine can provide ''visible nutrition information at the point of purchase'' for an article of food in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act, the preamble to the proposed rule noted that the phrase ''at the point of purchase'' suggests that ''the information, like the Nutrition Facts Panel, should be on the article of food itself'' (76 FR 19238 at 19244). We tentatively concluded that such information must be presented on the label of the food itself (76 FR 19238 at 19244). Under proposed § 101.8(b)(2), for nutrition information on the label to be considered ''visible,'' it would need, in relevant part, to be clear and conspicuous and easily read on the article of food while in the vending machine. Further, under proposed § 101.8(b)(2) a vending machine food would not be covered by the requirements of section 403(q)(5)(H)(viii) of the FD&C Act, as long as the food provides visible nutrition information ''at the point of purchase,'' and that the visible nutrition information ''appear[s] on the food label itself.''

The preamble to the proposed rule also stated that the phrase ''at the point of purchase'' could be read to mean that the visible nutrition information could be provided in places other than on the package of the food in the vending machine, such as on the vending machine itself (Id.). We invited comment on this alternative interpretation and specifically requested comment on whether, under this alternative interpretation, signs (including posters) or booklets would be sufficient in providing ''otherwise visible nutrition information at the point of purchase'' (Id.). We also requested comment on ways to determine if the nutrition information is ''visible'' (Id.).

Several comments asserted that any display (including a brochure, sign, or electronic display) of nutrition information at the point of purchase should exempt the vending machine operator from the calorie declaration requirements. The comments added that a display would not have to be on the package of the vending machine food itself, but could be nutrition information through other means, such as booklets.

One comment recommended that we define ''point of purchase'' as ''before and after the consumer inserts the required money, token, card, or key into the machine or manually operates it and before the consumer makes their final item selection.''

(Response 15) We disagree with the comments asserting that any display of nutrition information beyond the package of the food itself ''should exempt the vending machine operator from the calorie declarations requirements.'' As we noted in the proposed rule, in order for nutrition information to be ''visible'' at the point of purchase, the information must be clear and conspicuous and able to be easily read by a prospective purchaser (76 FR 19238 at 19244, 19254). Nutrition information in brochures or booklets would not be visible at the point of purchase in the same way that such information would be visible if presented on the label of a vending machine food, such as through FOP labeling. Nutrition information in a brochure or booklet would not be clear and conspicuous such that a prospective purchaser would be able to easily read the information when making a purchase selection as it would if the nutrition information were on the label of the food. In addition, brochures and booklets can be easily detached, lost, or otherwise absent, from a vending machine. For these reasons, we decline to include brochures and booklets within § 101.8(b)(2).

Regarding electronic displays of nutrition information, we note that proposed § 101.8(c)(2)(ii)(E) would provide that electronic vending machines (*i.e.,* machines with digital or electronic or liquid crystal display (LCD) displays) could be used to comply with the calorie declaration requirements in section 403(q)(5)(H)(viii) of the FD&C Act. As discussed further in section III.C.4.b.x of this preamble in connection with § 101.8(c)(2)(ii)(E), we conclude that electronic vending machines can be used to comply with the calorie declaration requirements in section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8(c). Further, electronic signs otherwise placed in, on, or adjacent to the vending machine can be used to provide calorie declarations under § 101.8(c), provided that such signs are located in close proximity to the article of food or the selection button, and otherwise comply with section 403(a)(1), (q)(5)(H)(viii), and (f) of the FD&C Act and the requirements of § 101.8(c). Because electronic vending machines and signs can be used to provide calorie declarations in accordance with § 101.8(c), it would be difficult and perhaps unnecessary for FDA to determine whether a vending machine operator is using such a method to provide ''visible nutrition information at the point of purchase'' in accordance with § 101.8(b) or to provide calorie declarations in accordance with § 101.8(c). For these reasons, we believe that it is unnecessary to include such electronic displays within § 101.8(b)(2).

Similarly, regarding non-electronic signs providing nutrition information, we note that § 101.8(c)(2) allows for the use of signs in, on, or adjacent to a vending machine to provide calorie declarations for covered vending machine food. Therefore, to the extent a vending machine operator provides calorie information for a vending machine food on such a sign and otherwise meets the requirements of section 403(a)(1), (q)(5)(H)(viii), and (f) of the FD&C Act and § 101.8(c), the operator would be in compliance with this rule. Because such signs can be used to provide calorie declarations in accordance with § 101.8(c), it would be difficult and perhaps unnecessary for FDA to determine whether a vending machine operator is using such a method to provide ''visible nutrition information at the point of purchase'' in accordance with § 101.8(b) or to provide calorie declarations in accordance with § 101.8(c). For these reasons, we believe that it is also unnecessary to include signs within § 101.8(b)(2).

As explained in the previous paragraphs, brochures, booklets, electronic displays, and non-electronic signs would not satisfy § 101.8(b)(2). Therefore we conclude, as we did in the proposal, that ''visible nutrition information at the point of purchase'' for an article of food sold from a vending machine must be presented on the label of the food itself.

Regarding the comment that would interpret ''point of purchase'' as a moment in time, we agree that ''point of purchase'' can be interpreted both with regard to a place (where the prospective purchaser buys the vending machine food item) and a time (when the prospective purchaser makes the selection). Accordingly, to provide visible nutrition information at the point of purchase, such information must be on the label of a food sold in a vending machine before the prospective purchaser makes a purchase. In order for a prospective purchaser to be able to view nutrition information on the label of a vending machine food at the point of purchase, the prospective purchaser must be able to read the nutrition information before purchasing the food, which typically

means that the vending machine would have to have a clear front so that the prospective purchaser would be able to see the information.

(Comment 16) The preamble to the proposed rule stated that FOP labeling could be a way to provide ''visible nutrition information'' so long as the criteria for color, font, and type size are met, and the total calories contained in the vending machine food are included (76 FR 19238 at 19244). We tentatively concluded that the visible nutrition information must be in a type size reasonably related to the most prominent printed matter on the label and in a color that sufficiently contrasts with the background, such that a prospective purchaser is able to notice and read the information (Id.). The preamble to the proposed rule explained that we consider ''reasonably related'' to mean a type size that is ''at least 50 percent'' of the size of the largest print on the label (Id.). We also noted that if a nutrient content claim or health claim is included on the front of the package, the claim must comply with relevant FDA regulations authorizing such claims (Id.).

Many comments supported the idea that FOP labeling could provide visible nutrition information, stating that FOP labeling is the most efficient way to satisfy section 403(q)(5)(H)(viii) of the FD&C Act. Other comments stated that vending machine operators are likely to prefer food products with FOP labeling because such labeling would exempt the operators from having to provide calorie declarations for such foods on signs under section 403(q)(5)(H)(viii)(I)(bb) of the FD&C Act. These comments added that vending machine operators may pressure food manufacturers to provide FOP labeling in exchange for product distribution in their vending machines.

Several comments argued that interpreting ''reasonably related'' to mean a type size that is at least 50 percent of the size of the largest print on the label would require a type size that is too large. One comment would revise the rule to specify a ratio for the size of the FOP calorie disclosure relative to other printed material on the label. The comment stated that ''reasonably related'' would be hard for inspectors to enforce and, therefore, FDA should require the FOP calorie disclosure to be at least two-thirds the size of the largest font size of any other writing on the package, and a minimum size of ½ square inch. Other comments said that the final rule should omit requirements for prominence or type size of the FOP calorie disclosure.

(Response 16) We agree that FOP labeling can be an efficient way to provide visible nutrition information within the context of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act, provided that the criteria for color and type size are met, and the total calories contained in the article of food are included. (We would not consider FOP labeling that provides only the calories per serving to count as ''visible nutrition information'' within the context of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act). Some manufacturers have already been including calories on their FOP labels. With respect to the comments concerning possible interactions between food manufacturers and vending machine operators, such interactions will depend on, and are best left to, vending machine operators and their suppliers.

In response to the comments regarding type size and prominence of the visible nutrition information on the label of the food, we have revised § 101.8(b)(2)(i) to replace the words ''reasonably related'' with ''at least 50 percent of the size of the largest printed matter on the label.'' Specifying the minimum type size for calorie information on vending machine food labels will provide greater clarity for both compliance and enforcement. While we recognize that some comments asserted that 50 percent of the size of the largest print on the label would result in type sizes that are too large, other comments asserted that the resulting type size would be too small, and some comments asked FDA to omit any requirements for prominence or type size.

Further, we clarify that section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act describes foods that are not subject to the vending machine labeling requirements specified in section 403(q)(5)(H)(viii) of the FD&C Act. Therefore, by specifying the type size of the visible nutrition information, we are not imposing any additional requirements on vending machine food. Instead, we are explaining when articles of food sold from vending machines satisfy the language of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act such that such foods are not covered by the labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act. In addition, there are other options that vending machine operators may choose to satisfy section 403(q)(5)(H)(viii) of the FD&C Act, including using a vending machine that provides electronic reproductions of Nutrition Facts labels, as provided in § 101.8(b)(1), or posting signs with calorie declarations, as provided in § 101.8(c).

We disagree with comments asking that we omit requirements for prominence or type size of FOP calorie disclosures for the purposes of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act. When a vending machine food is in a vending machine, a prospective purchaser cannot handle the product to make it easier for the purchaser to read the nutrition information. Therefore, ''visible nutrition information'' on the front of package must be large enough, and prominent enough, for prospective purchasers to see and use the information.

Furthermore, § 101.8(b)(2) requires the visible nutrition information to be ''clear and conspicuous and able to be easily read on the article of food while in the vending machine.'' Type size is one factor in determining whether the nutrition information on a food label is ''clear and conspicuous and easily read,'' and other considerations, such as color and contrasting background (which § 101.8(b)(2) also addresses), can affect the prospective purchaser's ability to read the nutrition information. For example, a prospective purchaser might be able to read nutrition information in one vending machine, but not in another vending machine if the first vending machine's design enabled the prospective purchaser to get close to the food label. In contrast, if a vending machine's design results in the food label being several inches away from the prospective purchaser, the nutrition information might not be as easy to read. The important consideration is to ensure that prospective purchasers are able to read and use the nutrition information for a vending machine food before purchasing the food.

4. Section 101.8(c)—Requirements for Calorie Labeling for Certain Food Sold From Vending Machines

Proposed § 101.8(c) would establish requirements for calorie declarations for foods sold from vending machines, as required by section 403(q)(5)(H)(viii) of the FD&C Act. In brief, proposed § 101.8(c)(1) would define ''covered vending machine food,'' and proposed § 101.8(c)(2) would establish requirements for calorie declarations on signs in, on, or adjacent to the vending machine.

a. *Covered vending machine food.* Proposed § 101.8(c)(1) would explain the ''applicability'' of the calorie labeling requirements to foods sold from vending machines by defining ''covered vending machine food'' as an article of food that is:

- Sold from a vending machine that:
  - Does not permit the consumer to examine the Nutrition Facts Panel prior to purchase as provided in paragraph (b) of this section, or otherwise provide

visible nutrition information at the point of purchase as provided in paragraph (b);

○ Is operated by a person engaged in the business of owning or operating 20 or more vending machines; and

○ Is a vending machine with a selection button; or

• Sold from a vending machine that is operated by a vending machine operator that has voluntarily elected to be subject to the requirements of this section by registering with FDA under the provisions of paragraph (d) of this section.

(Comment 17) The preamble to the proposed rule explained that the requirements of section 403(q)(5)(H)(viii) of the FD&C Act do not apply to vending machine operators who own or operate fewer than 20 vending machines that sell articles of food (76 FR 19238 at 19241). Thus, even if a vending machine operator has 50 vending machines, the operator is not subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act if fewer than 20 of those vending machines sell articles of food.

One comment asked us to clarify that a vending machine that dispenses a mix of food and non-food items would be considered a vending machine that sells articles of food when determining whether the vending machine operator is covered. The comment sought to ensure that all vending machines that dispense some articles of food would be covered, if applicable.

(Response 17) In general, § 101.8(a) defines a ''vending machine'' as a self-service device that dispenses ''servings of food in bulk or in packages, or prepared by the machine.'' This definition includes vending machines that sell both food and non-food items. However, section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8(c) only apply to certain vending machine foods and the operators of vending machines that sell such foods. A vending machine that sells an article of food will be counted towards the ''20 or more'' threshold for determining whether a vending machine operator is covered, even if the vending machine also sells non-food items, provided that such a vending machine does not dispense those food items as part of a game or other non-food related activity, as discussed further in the paragraphs that follow.

We are aware that ''game machines'' sometimes dispense candy or other edible items as part of a game or other non-food related activity. However, we conclude that ''game machines'' are not covered by section 403(q)(5)(H)(viii) of the FD&C Act, and do not count towards the ''20 or more'' threshold for determining whether a vending machine operator is covered. As we discussed in the preamble to the proposed rule (76 FR 19238 at 19241) and explain further in our response to comment 18, the primary purpose of a ''game machine'' is to sell a chance to play a game or to provide entertainment, and not to sell articles of food.

(Comment 18) In the preamble to the proposed rule, we tentatively concluded that vending machines that may dispense food as part of a game or other non-food related activity are not covered by section 403(q)(5)(H)(viii) of the FD&C Act (76 FR 19238 at 19241). For example, as we discussed in the preamble to the proposed rule, if a vending machine contains small toys and individually wrapped candies that can be picked up by maneuvering a large claw arm, we tentatively concluded that the vending machine is selling the opportunity to play the game, and not selling articles of food (76 FR 19238 at 19241).

One comment disagreed with our tentative conclusion in the proposed rule to not cover vending machines that may dispense food as part of a game or other non-food related activity (*e.g.,* claw games with candy prizes amongst other prizes). The comment claimed that a consumer playing a claw game could still maneuver the claw toward a healthier option if the calorie declarations for food prizes were available.

(Response 18) We decline to apply the requirements of section 403(q)(5)(H)(viii) of the FD&C Act to vending machines that may dispense food as part of a game or other non-food related activity. Section 403(q)(5)(H)(viii) of the FD&C Act applies to ''an article of food sold from a vending machine.'' FDA concludes that an article of food that may be dispensed from a vending machine as part of a game or other non-food related activity does not constitute ''an article of food sold from a vending machine'' within the context of section 403(q)(5)(H)(viii) of the FD&C Act. Game machines sell the opportunity to play a game or experience entertainment, and not the article of food itself. While the comment disagreeing with our conclusion indicated that calorie information might motivate an individual to ''maneuver the game claw towards a healthier option,'' the comment provided no basis to support this assumption. For these reasons, we are not amending the final rule to cover game machines, as suggested by the comment.

(Comment 19) The preamble to the proposed rule noted that section 403(q)(5)(H)(viii) of the FD&C Act provides that, for covered vending machine food, the vending machine operator must provide a sign disclosing the number of calories contained in the food ''in close proximity to each article of food or the selection button'' (76 FR 19238 at 19241). We tentatively concluded that the reference to ''selection button'' can be read to mean that only vending machines with selection buttons are subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. We indicated that we were not aware of vending machines without selection buttons other than bulk vending machines that dispense, by use of a crank, single types of unpackaged articles of food in preselected amounts (*e.g.,* a single piece of gum or a handful of candy or nuts). We tentatively concluded that vending machines without any type of selection button, including bulk vending machines, were not covered by section 403(q)(5)(H)(viii) of the FD&C Act, and we invited comment on this subject.

Some comments agreed with our interpretation of the reference to ''selection button'' in section 403(q)(5)(H)(viii) of the FD&C Act. The comments stated that, for bulk vending machines, a consumer only would be choosing whether to buy the bulk product and would not be selecting among food items; therefore, the button on such a vending machine would not constitute a ''selection button.'' The comments noted that bulk foods tend to be lower in calories because of the vended size (such as a small handful of nuts or candies) compared to other foods (such as candy bars or bags of chips) sold in typical vending machines. One comment asked that we exempt ''turret-style'' (turnstile) refrigerated food vending machines from the requirements of section 403(q)(5)(H)(viii) of the FD&C Act because such machines do not have selection buttons.

Other comments disagreed with our interpretation of the reference to ''selection button'' in section 403(q)(5)(H)(viii) of the FD&C Act, and argued that the lack of a selection button does not justify an exemption from the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. These comments also asserted that there would be no public health rationale for such an exemption. Some comments asserted that the mention of a selection button in section 403(q)(5)(H)(viii) of the FD&C Act was not intended to differentiate between ''regular'' vending machines (*i.e.,* those that have selection buttons) and machines that use a device

other than a selection button. The comments said that the statute's mention of a selection button was meant to refer to where the nutrition information should be placed. These comments also said that bulk items (usually candy and gumballs) are appealing to children, so calorie information should be made available. They also urged FDA to maintain consistency by requiring calorie labeling for all types of vending machines. In addition, one comment pointed out that excluding vending machines without a selection button would give bulk vending machines an unfair advantage over ''traditional'' (*i.e.,* non-bulk) vending machines because the operators of bulk vending machines would not have to incur any expenses to implement the calorie declaration requirements.

Other comments noted that complying with the calorie labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act would not be burdensome for a bulk machine vending machine operator because such a machine generally only dispenses one product (*e.g.,* nuts, gumballs), and consumers do not select between multiple items. Therefore, several comments asserted that a vending machine operator for a bulk vending machine would only have to affix one sticker or decal displaying the calorie declaration on the bulk machine.

(Response 19) Section 403(q)(5)(H)(viii) of the FD&C Act provides that, for covered vending machine food, the vending machine operator must provide a sign disclosing the number of calories contained in the food ''in close proximity to each article of food or the selection button.'' Although in the proposed rule, we tentatively concluded that vending machines without selection buttons are not covered, upon further consideration and in light of the comments asserting that the presence or absence of a selection button should not determine whether a vending machine is subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act, this final rule provides that covered vending machines also include those without selection buttons.

In construing whether vending machines without selection buttons are within the scope of section 403(q)(5)(H)(viii) of the FD&C Act, we are confronted with two questions. First, has Congress directly spoken to the precise question presented (''*Chevron* step one'') *Chevron, U.S.A., Inc.* v. *NRDC.,* 467 U.S. 837, 842 (1984). If Congress has spoken directly and plainly, the Agency must implement Congress's unambiguously expressed intent. *Chevron,* 467 U.S. at 842–843. If, however, Congress is silent or ambiguous as to the question, our interpretation will be upheld as long as it is based on a ''permissible construction'' of the statute. (''*Chevron* step two''). *Chevron,* 467 U.S. 843–844; *FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 132 (2000).

We have determined that, in enacting section 403(q)(5)(H)(viii), Congress did not speak directly and plainly to the question of whether vending machines without selection buttons are covered. In conducting the Chevron step one analysis, all the traditional tools of statutory construction are available, *e.g.,* the statute's text, structure, and legislative history. *Pharmaceutical Research & Manufacturers of America* v. *Thompson,* 251 F. 3d 219, 224 (D.C. Cir. 2001). The term ''vending machine'' as used in section 403(q)(5)(H)(viii) is not specific as to whether it must have a selection button. The scant legislative history does not shed any light on whether Congress intended to limit covered vending machines only to those with selection buttons by virtue of the statutory provision regarding the placement of the calorie declaration sign in close proximity to the selection button.

Having determined that Congress's intent regarding whether vending machines without selection buttons are required to have calorie declaration signs is ambiguous, we have determined that the final rule's interpretation of covered vending machine as any machine regardless of whether it has a selection button is a permissible construction of the statute. (*Chevron* step two). In conducting the Chevron step two analysis, the same tools of statutory construction are available as those for the step one analysis.

The interpretation in the final rule is consistent with the plain meaning of the statute, which is the starting point of statutory construction. (*See* 2A Sutherland Statutory Construction 137 (7th ed. 2007). Section 403(q)(5)(H)(viii) uses the term ''vending machine'' in three instances. It refers to ''an article of food sold from a vending machine.'' It refers to ''a person who is engaged in the business of owning or operating 20 or more vending machines.'' Finally, the statute refers to ''the vending machine operator.'' In the two instances in which the statute refers to ''vending machines,'' it does so without qualification or limitation on the type of machine.

Our interpretation is also consistent with the structure of the statute which identifies only two limitations that apply to the vending machines. Those limitations are set out in section 403(q)(5)(H)(viii)(I)(aa) and (bb) of the FD&C Act. The provisions state that an article of food requires a calorie declaration if it is ''from a vending machine that (aa) does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase; and (bb) is operated by a person who is engaged in the business of owning or operating 20 or more vending machines.'' That is, the vending machines not subject to the calorie labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act are those that allow the prospective purchaser to examine the Nutrition Facts label or does not otherwise provide visible nutrition at the point of purchase or those that are operated by a person in the business of owning or operating less than 20 vending machines. Although these provisions address covered vending machines, they do not address a type of vending machine.

Accordingly, we are interpreting section 403(q)(5)(H)(viii) of the FD&C Act to include vending machines with or without selection buttons.

As for the comments asserting that vending machines without selection buttons should not be covered by the requirements of section 403(q)(5)(H)(viii) of the FD&C Act because articles of food sold from bulk vending machines tend to contain fewer calories than foods sold in non-bulk vending machines, we clarify that section 403(q)(5)(H)(viii) of the FD&C Act does not exclude articles of food that contain low levels of calories from the calorie labeling requirements. Consistent with section 403(q)(5)(H)(viii) of the FD&C Act's general purpose to provide calorie information for foods sold from certain vending machines, we interpret section 403(q)(5)(H)(viii) of the FD&C Act to apply to vending machines that sell articles of food regardless of the food's caloric content and regardless of whether the vending machine has a selection button.

Further, we agree with the comments asserting that excluding vending machines without selection buttons from the requirements of § 101.8(c) is not supported by a public health rationale. Providing such calorie declarations will make calorie information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices. In addition, we agree with the comments stating that

providing calorie information would not be overly burdensome for bulk vending machine operators because such operators can use single stickers or decals to provide the required calorie declarations.

For these reasons, we have revised § 101.8(c)(1) by removing the criterion that a food must be sold from a vending machine with a selection button to be covered by the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. Additionally, because the final rule covers vending machines regardless of whether they have selection buttons, we decline to exempt turret-style or turnstile vending machines.

We also have revised § 101.8(c)(1)(i) and (ii), on our own initiative, to clarify the applicability of the rule. Proposed § 101.8(c)(1)(i) would address vending machines operated by persons who must comply with section 403(q)(5)(H)(viii) of the FD&C Act, and proposed § 101.8(c)(1)(ii) would address vending machines operated by persons who voluntarily register with FDA to become subject to section 403(q)(5)(H)(viii) of the FD&C Act. However, the conditions under which an article of food would not be covered by the rule (if the article of food permits the prospective purchaser to examine the Nutrition Facts label before purchase as provided in proposed § 101.8(b)(1), or otherwise provides visible nutrition information at the point of purchase as provided in proposed § 101.8(b)(2)), were contained in proposed § 101.8(c)(1)(i)(A) and therefore would not have appeared to be applied to persons who voluntarily registered with FDA. As a result, we have reorganized and revised § 101.8(c)(1)(i) to describe the provisions in § 101.8(b) under which an article of food is not covered by the rule. We also have reorganized and revised § 101.8(c)(1)(ii) to refer to the two types of vending machine operators that may be subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act (those required to comply by law and those who may register voluntarily to comply with the requirements). We have connected § 101.8(c)(1)(i) and (ii) with the conjunction ''and'' to specify that the provisions in § 101.8(b) may apply to both types of covered vending machine operators.

On our own initiative, we also have made an editorial change to replace ''the FDA'' with ''FDA.'' Also, we have replaced ''consumer'' with ''prospective purchaser'' to be consistent with the rest of the final rule, and have specified paragraphs ''(b)(1)'' and ''(b)(2)'' where these provisions are summarized (rather than referring to them both as ''paragraph (b)''), and we have changed ''Nutrition Facts Panel'' to ''Nutrition Facts label'' to match terms used in the rest of the final rule.

b. Calorie declaration. Proposed § 101.8(c)(2) would establish requirements for calorie declarations for covered vending machine food.

i. *Calorie increments.*

Proposed § 101.8(c)(2)(i)(A) would require the calorie declaration to be ''clear and conspicuous'' and declared to the ''nearest 5-calorie increment up to and including 50 calories and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero.''

In the preamble to the proposed rule, we tentatively decided against allowing ranges for declaring calories for vending machine food that comes in different varieties and flavors (*e.g.,* coffee or hot chocolate) (76 FR 19238 at 19242). We noted in the preamble of the proposed rule that a ''vending machine operator could post a calorie declaration in close proximity to the selection button for a food that comes in different varieties and flavors that is sold in a vending machine that has selection buttons corresponding to the different options'' (Id.). Therefore, the vending machine operator could provide calorie declarations for each variety or option adjacent to selection buttons corresponding to each option (Id.). Further, we tentatively concluded that calorie ranges are also not necessary within the context of vending machines because a vending machine operator would be able to disclose calorie information under other options (*e.g.,* use of signs) (Id.).

(Comment 20) Some comments agreed with FDA's tentative conclusion in the proposed rule and stated that a range or an average would not be necessary. These comments stated that in situations where items are displayed such that multiple flavors or varieties exist in the same space, different selection buttons provide the opportunity for the operator to list separate calorie information for each item, and therefore ranges or averages for these vending machines would not be necessary.

A few comments disagreed with FDA's tentative conclusion in the proposed rule and recommended that we allow the use of ranges. The comments stated that slight variations will occur such as in fresh coffee vending machines where different types of creamer or flavoring may be used.

Some comments asked that we exempt self-service, custom order vending machines that allow the customer to select size, type of drink, type of milk, and additional flavors from the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. The comments claimed it would not be feasible for operators of such vending machines to declare calories for all the possible customizations due to lack of space on the vending machine. According to one comment, disclosing calories for customizations can be inaccurate and misleading. For example, the comment asserted that adding syrup to a drink displaces a portion of the beverage that would have otherwise been included in the cup, and as a result some customizations do not add calories to the finished beverage. According to the comment, adding sugar-free syrup actually reduces the beverage's calories. Because FDA proposed to not apply the nutrition labeling requirements of section 403(q)(5)(H)(i)–(vii) of the FD&C Act (relating to standard *menu* items offered for sale in restaurants and similar retail food establishments) to custom orders, the comments argued that we should similarly exempt custom beverage vending machines from the vending machine labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act. The comments said that if we do not exempt such vending machines, we should give vending machine operators the flexibility to choose the method of calorie information disclosure for highly customizable self-serve products. For example, vending machine operators should be permitted to simply disclose calorie content for the condiments offered for customization, *e.g.,* calories per ounce of milk or per shot of syrup.

(Response 20) We conclude that calorie ranges are not necessary for vending machine foods that come in different varieties and flavors. Unlike section 403(q)(5)(H)(v) of the FD&C Act—which pertains to nutrition labeling for standard menu items offered for sale in restaurants and similar retail food establishments and allows FDA to establish standards for disclosing the nutrient content for certain standard menu items that come in different flavors, varieties, or combinations, through means determined by FDA, including ranges, averages, or other methods—section 403(q)(5)(H)(viii) of the FD&C Act specifies that, if covered, a vending machine operator must provide a sign disclosing the number of calories contained in an article of food sold from a vending machine.

We also decline to permit calorie ranges because, as noted by the comments, vending machine operators can declare calories for each ''option'' offered. For a vending machine that has selection buttons corresponding to different options, a vending machine

operator could post a calorie declaration in close proximity to the corresponding selection buttons. In addition, vending machines that dispense various flavors or varieties of beverages do so in measurable quantities; therefore, it is reasonable to require vending machine operators to provide calorie declarations for such options. To give vending machine operators flexibility, the final rule allows vending machine operators to declare calories per option or for the final vended products. For example, if a vending machine dispenses coffee products with options for adding skim milk, whole milk, cream, sugar, or sugar substitute, the vending machine operator could provide calorie declarations for each of those added options individually. If the vending machine operator chose to declare calories for the final vended products sold from the machine, the calorie declarations would be for all final vended coffee products sold from the machine, meaning all dispensed combinations of coffee, skim milk, whole milk, cream, sugar, and sugar substitute. Note that a vending machine operator could post calorie declarations next to each selection button, or on a sign in, on, or adjacent to the vending machine, as provided in § 101.8(c).

We decline to exempt the types of self-service, custom-order vending machines described by the comments from the calorie labeling requirements for vending machine food of section 403(q)(5)(H)(viii) of the FD&C Act. As a preliminary matter, we clarify that while section 403(q)(5)(H)(vii)(I)(bb) of the FD&C Act, which pertains to restaurants and similar retail food establishments, provides that the nutrition labeling requirements of sections 403(q)(5)(H)(i) through (vi) of the FD&C Act for standard menu items do not apply to ''custom orders'', the vending machine food labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act do not provide for such an exclusion. Furthermore, in the proposed rule for nutrition labeling of standard menu items in restaurants and similar retail food establishments (76 FR 19192, April 6, 2011), we proposed to define ''custom order'' as a food order that is prepared in a specific manner based on an individual customer's request, which requires the restaurant or similar retail food establishment to deviate from its usual preparation of a menu item (76 FR 19192 at 19233). The ''custom orders'' for purposes of nutrition labeling of standard menu items in restaurants and similar retail food establishments are not equivalent to vending machine foods that come in different varieties or flavors because such vending machine foods are not prepared in a way that deviates from a usual preparation of the item. Instead, vending machines offering articles of food in different varieties or flavors generally are programmed to dispense measurable quantities of beverages, flavors, or other varieties at the customer's selection. As such, a vending machine operator can declare calories for each variety or flavor on a sign in close proximity to the selection buttons for such varieties and flavors or on a sign adjacent to the vending machine, as provided by § 101.8(c).

In consideration of the comments asking for flexibility for these products, and to provide clarity, we have added a new § 101.8(c)(2)(i)(D). (We have renumbered proposed § 101.8(c)(2)(i)(D) as § 101.8(c)(2)(i)(C) in the final rule, as will be discussed in response 23, and removed proposed § 101.8(c)(2)(i)(E) as will be discussed in response 24). Section 101.8(c)(2)(i)(D), as finalized, provides that if a covered vending machine food is one where the prospective purchaser selects among options to produce a final vended product (*e.g.,* vended coffee, hot chocolate or tea with options for added sugar, sugar substitute, milk, and cream), calories must be declared per option or for the final vended products.

Regarding the comments asserting that it would not be feasible for vending machine operators to declare calories for each variety or flavor due to lack of space on the vending machine, we note that vending machine operators may place a sign declaring calories adjacent to the vending machine, as provided in § 101.8(c). We further discuss the placement of signs disclosing the number of calories in covered vending machine food in our response to comment 28. We also note that vending machine operators have flexibility to declare either the calories from each option or the calories for final vended products.

Consequently, we have finalized § 101.8(c)(2)(i)(A) without change. However, on our own initiative, we have moved the requirement in the introductory sentence of proposed § 101.8(c)(2)(i) that the number of calories ''must be clear and conspicuous,'' and placed it instead in the introductory sentence of § 101.8(c)(2)(ii) of the final rule. The ''clear and conspicuous'' standard more appropriately reflects the requirements in § 101.8(c)(2)(ii), which focus on the placement and appearance of the calorie declarations, rather than the requirements of § 101.8(c)(2)(i), which focus on the content of the calorie declarations.

ii. *Use of the term ''Calories'' or ''Cal''.*

Proposed § 101.8(c)(2)(i)(B) would require that the term ''Calories'' or ''Cal'' appear adjacent to the caloric content value for each food in the vending machine.

We received no comments on this provision and have finalized it without change.

iii. *Calorie declaration type size, color, and contrast.*

Proposed § 101.8(c)(2)(i)(C) would specify the calorie declaration's type size, color, and contrast. For calorie declarations in or on the vending machine, the proposal would require the calorie declaration to be in a type size no smaller than the name of the food on the machine, not the label, selection number, or price of the food as displayed on the vending machine, whichever is smallest, with the same prominence, *i.e.,* the same color, or in a color at least as conspicuous, as the color of the name, if applicable, or price of the food or selection number, and the same contrasting background, as the item it is in closest proximity to, *i.e.,* name, selection number, or price of the food item as displayed on the machine (76 FR 19238 at 19254).

(Comment 21) Many comments agreed with the proposed requirements for type size, color, and contrast for calorie declarations in or on the vending machine. However, some comments argued that the calorie declaration should be more prominent. Several comments suggested that we revise the rule to state that ''calorie labeling be as large as the name of the vended item if it is posted on the machine, selection number, or the price, whichever is largest.'' One comment said that the font, size, and color of the calorie declaration should be no less prominent than the price, label (although the comment did not describe what it meant by ''label''), or item name. Another comment said that the calorie declaration must be large enough to read from a ''normal standing posture.''

Other comments said the proposed rule was too restrictive and wanted greater flexibility for the type size of the calorie declaration—whether on the vending machine or on the food itself. Several comments claimed that the proposed rule would force vending machine operators to make significant changes to the size of product brand names on smaller vending buttons or use ''distractingly large'' calorie declarations on certain larger vending buttons. (We interpret the comment's

reference to ''vending button'' to be the same as a selection button.)

Regarding the proposed requirement for contrasting background, one comment stated that the calorie declaration should have a contrasting background and be in a font color that is at least as visible as, rather than the same as, the background and the color of the selection number or price.

(Response 21) The preamble to the proposed rule explained that for calorie declarations in or on the vending machine, the calorie declaration must be in a type size ''no smaller than the name, selection number, or price of the food as displayed on the vending machine, whichever is smallest'' (76 FR 19238 at 19243). Proposed § 101.8(c)(2)(i)(C) would state, in relevant part, that the declaration of calories must be in a type size no smaller than the name of the food on the machine, not the label, selection number, or price of the food as displayed on the vending machine, whichever is smallest. To further clarify that the type size of the calorie declarations must be in a type size no smaller than the name of the food on the machine, the selection number, or the price of the food as displayed on the vending machine, whichever is smallest, we have revised the provision that was proposed § 101.8(c)(2)(i)(C) (which is moved and consolidated as § 101.8(c)(2)(ii)(B) in this final rule, as explained later in this response) to place the phrase ''not the label'' in parentheses. We are connecting the calorie declaration's type size to the type size of other information on the vending machine that a prospective purchaser uses to make a selection (*i.e.,* the name of the food on the machine, the selection number, the price of the food as displayed), in order to ensure that the calorie declaration is clear and conspicuous and similarly readable.

We decline to make the changes requested by the comments to the requirements for size and color of the calorie declarations in or on the vending machine because the comments did not provide any specific information regarding the size or color of the calorie declarations, particularly information that would give us a basis to revise the rule. For example, the comments asserting that calorie declarations should be larger or more prominent did not provide any information to show that the proposed requirements would not ensure that the calorie declarations are clear and conspicuous and easily readable.

In addition, with respect to the comment asserting that the calorie declaration must be large enough to be seen from a ''normal standing posture,'' such a standard would not take into account that there are different types of vending machines and that consumers vary in height and visual acuity. For example, calorie declarations at the top of a vending machine that a tall consumer might see easily could be difficult for a comparatively shorter consumer to see.

As for the comments seeking greater flexibility for vending machine operators, the requirements for the type size, color, and contrast of calorie declarations in or on the vending machine provide vending machine operators with flexibility by linking such requirements to the information that prospective purchasers otherwise use to make selections. Vending machine operators can therefore use the information (*i.e.,* the name of the food, selection number, or price of the food as displayed) that is already on their vending machines as a guide to comply with the type size, color, and contrast requirements for the calorie labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act for calorie declarations in or on the vending machine. This flexibility should enable vending machine operators to develop signs declaring calories for calorie declarations in or on the vending machine regardless of the type of vending machine they have. In addition to providing flexibility, the requirements, as finalized, help ensure that calorie declarations are clear and conspicuous, as required by section 403(q)(5)(H)(viii) of the FD&C Act.

In consideration of the comment asking that the contrasting background be ''at least as visible as'' (rather than ''the same as'') the background of the accompanying food item (*i.e.,* its name, selection number, or price), we have revised the provision that was proposed § 101.8(c)(2)(i)(C) (which is moved and consolidated as § 101.8(c)(2)(ii)(B) in this final rule, as explained later in this response) to require that the calorie declaration have the same contrasting background, or a background as least as contrasting as the background used for the item it is in the closest proximity to, *i.e.,* name, selection number, or price of the food item as displayed on the machine. Revising the rule in this manner provides additional flexibility related to the prominence requirements, and parallels the rule's requirement that the color of the calorie declaration be the same or ''at least as conspicuous'' as that of the accompanying food item's name, price, or selection number on the vending machine.

On our own initiative, we are also revising the rule to eliminate a duplicate requirement. Proposed § 101.8(c)(2)(i)(C) would describe the type size, color and contrast for calorie declarations in or on the vending machine, and proposed § 101.8(c)(2)(ii)(B) would describe the color and contrast requirement for calorie information in or on the vending machine. Organizationally, proposed § 101.8(c)(2)(i) would focus on the content of the calorie declarations, and proposed § 101.8(c)(2)(ii) would focus on the placement and appearance of the calorie declarations. Therefore, for clarity, we are moving and consolidating proposed § 101.8(c)(2)(i)(C) with proposed § 101.8(c)(2)(ii)(B) to eliminate the duplicate requirement, and renumbering subsequent paragraphs that were proposed § 101.8(c)(2)(i)(D) and (E) to be § 101.8(c)(2)(i)(C) and (D) in the final rule.

For these reasons, under § 101.8(c)(2)(ii)(B) of the final rule, when the calorie declaration is in or on the vending machine, the calorie declaration must be in a type size no smaller than the name of the food on the machine (not the label), selection number, or price of the food as displayed on the vending machine, whichever is smallest, with the same prominence, *i.e.,* the same color, or in a color at least as conspicuous, as the color of the name, if applicable, or price of the food or selection number, and the same contrasting background, or a background at least as contrasting as the background used for the item it is in closest proximity to, *i.e.,* name, selection number, or price of the food item as displayed on the machine.

iv. *Calorie declarations for single-serving packaged food.*

Proposed § 101.8(c)(2)(i)(D) would state that the number of calories for single-serving packaged food declared on the sign must be identical to the number of calories that are declared in the Nutrition Facts, if applicable. Because section 403(q)(5)(H)(viii) of the FD&C Act refers to ''an article of food sold from a vending machine,'' the preamble to the proposed rule also indicated that calorie information must include the total calories present in the covered vending machine food as it is vended (76 FR 19238 at 19242). For example, for bundled items such as sandwiches that are dispensed with a single serving unit of a condiment (*e.g.,* mayonnaise), the calorie declaration must include the total calories in the sandwich plus any condiment packets bundled with it as a vended article (76 FR 19238 at 19242).

(Comment 22) One comment stated that calorie ranges are necessary with certain foods, such as fresh fruit, cotton

candy, sandwiches, or pastries because such foods can have slight calorie variations. The comment stated that vending machine operators need flexibility to declare calories in ranges and that ranges will make it easier for vending machine operators to implement the calorie labeling requirements.

(Response 22) We recognize that certain vending machine foods, such as fresh fruit, may have naturally occurring variations in calorie content depending on the size of the fruit and other factors. This is different from the situation of a food with various options that a consumer selects (as discussed in comment and response 20), and from the situation of a food that comes bundled with various components (as discussed in comment and response 23). We conclude that a range is not necessary for calorie declarations for vending machine foods that may have naturally occurring variations in calorie content depending on the size of the fruit or other factors. As discussed further in comment and response 34 in section III.D entitled ''Determination of Calorie Content,'' a vending machine operator may rely on a number of means to determine the calorie content of covered vending machine food. For example, a vending machine operator may obtain calorie information from nutrient databases, such as the ''USDA National Nutrient Database for Standard Reference'' (*http://ndb.nal.usda.gov/*) and use such information in declaring calories, provided that the calorie declarations are truthful and not misleading and otherwise in compliance with section 403(a)(1), (q)(5)(H)(viii), and (f) of the FD&C Act and § 101.8.

With respect to a potential variation in prepared food such as cotton candy, sandwiches, and pastries, we also conclude that a range is not necessary for calorie declarations for such foods. As discussed further in comment and response 34 in section III.D entitled ''Determination of Calorie Content,'' vending machine operators may be able to use various means to determine the calorie content for vending machine foods. For example, if the food is manufactured, the vending machine operator may be able to obtain the necessary calorie information from the food package's Nutrition Facts label, the manufacturer, or nutrient databases. It is the vending machine operator's responsibility to ensure that calorie declarations for foods are accurate and otherwise in compliance with section 403(a)(1), (q)(5)(H)(viii), and (f) of the FD&C Act and § 101.8.

(Comment 23) For vending machine foods such as sandwiches that consist of more than one separately packaged component and are sold as one unit in turnstile vending machines, one comment asked us to allow the vending machine operator to either: (1) Declare the total calories of the food as vended or (2) declare calories for each individual component. The comment said this would, for example, allow mayonnaise already on the sandwich to be included in the calories for the total package and also allow mayonnaise in a separate packet to be excluded from the calorie count of a sandwich that does not already have mayonnaise on it.

The comment further stated that allowing vending machine operators to declare calories for the components of a covered vending machine food separately would give the consumer more information. (The comment referred to its suggestion as ''itemized'' calorie declaration.) For example, according to the comment, a 428 calorie turkey sandwich with two packets of mayonnaise and two packets of mustard derives 250 calories from the sandwich itself, 86 calories from each packet of mayonnaise, and 3 calories from each packet of mustard. The comment said that it would be simpler for the vending machine operator to declare the calories for the primary item and for each separately packaged item that is provided because the operator would not need multiple versions of posters, labels, etc. depending on the types and quantities of condiments provided. The comment argued that such an approach for articles of food with multiple components, like sandwiches, would be consistent with FDA's approach to covered vending machine foods that come in different varieties and flavors, such as hot beverages, which FDA concluded, in the preamble to the proposed rule, could be declared per option (*e.g.,* cream for coffee). The comment asked that we revise the rule to give turnstile vending machines flexibility to declare calories separately for condiments sold with a food item.

(Response 23) We disagree with the comment asking us to allow the vending machine operator to either: (1) Declare the total calories of a bundled vending machine food as vended, or (2) declare calories for each individual component of a bundled vending machine food as vended. The requirements of section 403(q)(5)(H)(viii) of the FD&C Act apply, in relevant part, ''in the case of an article of food sold from a vending machine.'' Regarding a vending machine food that consists of more than one separately packaged component and is sold as one unit (*e.g.,* sandwich dispensed with a single serving packet of condiment), the calorie declaration for the food must include the total calories present in the food as it is vended, including the calories present in single serving units of condiments. We consider a packaged or plastic-wrapped sandwich including, if sold along with the sandwich, any packet(s) of condiments to be the ''article of food'' for purposes of applying the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. As such, the vending machine operator must provide a calorie declaration for the ''article of food'' as it is vended, which includes the calorie content of each component of the ''article of food.''

We will not object, however, if the vending machine operator voluntarily declares the calories for a bundled vending machine food that consists of more than one separately packaged component on a per packaged component basis, so long as the vending machine operator also provides the total calorie declaration for ''the article of food'' as it is vended. We note that condiment packets that are not dispensed with the sandwich (*e.g.,* those condiments that are stocked in a common area near a bank of vending machines) are not part of ''the article of food'' for purposes of applying the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. In such an instance, the vending machine operator should not include the condiment packets in the total calories of the article of food.

Further, contrary to the comment's assertion, requiring the calorie declaration for a bundled vending machine food to include the total calories present in the food as it is vended is not inconsistent with the calorie labeling requirements for articles of vending machine food that come in different varieties or flavors (*e.g.,* coffee), which we discussed in our response to comment 20. When the consumer affirmatively can choose the varieties or options dispensed with the food by pressing a selection button corresponding to each variety or option, the vending machine operator may display the calorie declarations for each variety or option in close proximity to the corresponding selection buttons for such varieties or options; however, when the consumer receives a bundled food item (such as a sandwich with a mayonnaise packet accompanying the sandwich), the consumer has selected to receive the food item as dispensed, and therefore, it is appropriate to label the calories for the entire bundled food item.

We also disagree with the comment stating that calorie ranges are necessary for certain foods, such as sandwiches. In

the case of bundled items, the consumer is unable to customize the item that is vended until after it is dispensed, and, therefore, a declaration of total calories is appropriate rather than a range. In the case of bundled items, as we have indicated, we would not object to additional calorie declarations for each component of a bundled item, as long as the vending machine operator also provides the total calorie declaration for the bundled item, as it is vended.

As discussed in response 21, we have moved what had been proposed as § 101.8(c)(2)(i)(C) and therefore we are renumbering proposed § 101.8(c)(2)(i)(D) as § 101.8(c)(2)(i)(C). Also, as discussed further in section III.C.4.b.v, we have made changes to renumbered § 101.8(c)(2)(i)(C) to further clarify that a calorie declaration for a covered vending machine food must include the total number of calories for the food, whether the food is a single-serving or multiple serving food. Section 101.8(c)(2)(i)(C) of this final rule provides that the number of calories for a covered vending machine food must include the total calories present in the food. As discussed in section III.D, a vending machine operator may determine the total calories contained in a covered vending machine food through a variety of methods, including obtaining the calorie information from the food package's Nutrition Facts label, the manufacturer or supplier of the food, nutrient databases, cookbooks or laboratory analyses. Covered vending operators must ensure that the calorie declarations are truthful and not misleading, as required by section 403(a)(1) of the FD&C Act, and otherwise comply with section 403(q)(5)(H)(viii) and (f) of the FD&C Act and § 101.8.

v. *Calorie declarations for packaged food having multiple servings.*

Proposed § 101.8(c)(2)(i)(E) would require that the calorie declaration for a covered vending machine food that contains multiple servings include the total number of calories present in the vending machine food. Proposed § 101.8(c)(2)(i)(E) would also allow vending machine operators to voluntarily disclose the calories per serving in addition to the total calories for the food.

(Comment 24) Many comments stated that vending machine food, regardless of its serving size, is typically consumed in one occasion. The comments agreed with proposed § 101.8(c)(2)(i)(E) and said that section 403(q)(5)(H)(viii) of the FD&C Act's reference to an ''article of food sold from a vending machine'' and disclosure of calories contained in the article indicates that a vending machine operator must declare the total calories contained in a vending machine food as it is packaged for sale, or otherwise sold from a vending machine, even if the food's Nutrition Facts label states that the food contains more than one serving. Similarly, because vending machine food is typically consumed in one occasion, a few comments noted that declaring calories per serving could be potentially confusing to consumers. The comments stated that it would be deceptive, for example, to label a bag of chips as 160 calories (per one-ounce serving) on the vending machine, only to have people discover that the whole bag of chips contained 1.5 servings and 240 calories.

Other comments disagreed with proposed § 101.8(c)(2)(i)(E). The comments would base calorie declarations on the serving size listed on the Nutrition Facts label and said that doing so would be consistent with current nutrition labeling requirements. The comments pointed out that some commonly vended foods contain more than one serving and that, for those foods, the calories as listed per serving in the Nutrition Facts label would not be identical to the calorie declaration disclosing the number of calories contained in the entire article of food.

In contrast to the comments asserting that vending machine foods typically are consumed in their entirety in one occasion, regardless of listed servings on the package, a few comments stated that labeling total calories for foods such as gum would be misleading because typically, people do not chew the entire pack of gum in one occasion and that calories should be allowed to be displayed per serving.

Several comments supporting calorie declarations per serving noted that Congress used the term ''item'' for the nutrition labeling requirements for standard menu items offered for sale in restaurants and similar retail food establishments of section 4205 of the ACA, but used the term ''article'' for the vending machine food labeling requirements. One comment stated that because Congress used different words to express the two requirements, the words should have different meanings. The comment contended that ''article,'' which is used in the vending machine labeling requirements of section 4205 of the ACA, suggests that the number of calories per serving, and not the total number of calories contained in the food, must be declared. The comment also noted that the nutrition labeling requirements for packaged foods is per serving. According to the comment, if FDA thinks per serving calorie declarations are not sufficient, we should address the issue directly through our serving size regulations and not indirectly through the vending machine calorie declaration requirements.

(Response 24) We decline to revise the rule to require the calorie declarations for covered vending machine food to be based on the serving size listed on the Nutrition Facts label. We agree with the comments asserting that many vending machine foods are typically consumed in one occasion. Further, we note that the requirements of section 403(q)(5)(H)(viii) of the FD&C Act apply to an ''article of food sold from a vending machine,'' and section 403(q)(5)(H)(viii) of the FD&C Act requires a vending machine operator to disclose the ''number of calories contained in the article [of food].'' Thus, we conclude that section 403(q)(5)(H)(viii) of the FD&C Act requires that the calorie declaration for an article of food sold from a vending machine, including foods that contains multiple servings, be equal to the total ''number of calories contained in the article [of food]'' as dispensed, rather than the number of calories contained in the serving size, if applicable, for the food. The total number of calories can be determined by multiplying the number of calories per serving by the number of servings in the package. For example, if the Nutrition Facts for an article of food states 80 calories per serving and 3 servings per container, the total number of calories in the entire package would be 240 calories.

Further, regarding the comments supporting calorie declarations per serving because Congress used the term ''item'' for the nutrition labeling requirements for standard menu items offered for sale in restaurants and similar retail food establishments of section 4205 of the ACA, but used the term ''article'' for the vending machine food labeling requirements, we disagree with the comments. First, the language of section 403(q)(5)(H)(viii) of the FD&C Act generally provides, in relevant part, that ''[i]n the case of an article of food sold from a vending machine . . . the vending machine operator shall provide a sign in close proximity to each article of food or the selection button that includes . . . the number of calories *contained in the article [of food].''* (Emphasis added.) Therefore, the calorie declaration must include the number of calories contained in the article of food, and not the number of calories per serving of the food.

Second, the fact that Congress used the term ''menu item'' in section 403(q)(5)(H)(i)–(vii) of the FD&C Act does not indicate that ''article of food''

should be interpreted to mean ''per serving'' within the meaning of section 403(q)(5)(H)(viii) of the FD&C Act. If Congress intended to require calories to be declared in serving size amounts, Congress could have used specific language to indicate this intent, as demonstrated elsewhere in section 403(q) of the FD&C Act (''serving size,'' ''number of servings,'' and ''per serving'' in section 403(q)(1)(A) and (q)(5)(H)(iii) of the FD&C Act). Such an omission indicates that declaring calories in serving size amounts was not the intent of Congress. E.g., *Russello* v. *U.S.,* 464 U.S. 16, 23 (1983) (''[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion'') (citation omitted).

We reiterate, however, that proposed § 101.8(c)(2)(i)(E) (which has been consolidated with proposed § 101.8(c)(2)(i)(D) and renumbered as § 101.8(c)(2)(i)(C) in the final rule, as explained further in the paragraphs that follow) would allow for the voluntary declaration of calories per serving for covered vending machine foods. Regarding the comment suggesting that we revise our serving size regulations, we clarify that this rule implements the requirements of section 403(q)(5)(H)(viii) of the FD&C Act for foods sold in vending machines. For the purposes of this rule, calorie declarations for covered vending machine foods must be provided for the total number of calories contained in the article of food.

As discussed in response 21 of this preamble, we have moved proposed § 101.8(c)(2)(i)(C) and therefore have renumbered proposed § 101.8(c)(2)(i)(D) as § 101.8(c)(2)(i)(C). Additionally, for the reasons noted in the previous paragraphs, and as discussed in section III.C.4.b.iv, we have made changes to renumbered § 101.8(c)(2)(i)(C) to further clarify that a calorie declaration for a covered vending machine food must include the total number of calories for the food, whether the food is a single serving or multiple serving food. In addition, we have added a sentence to § 101.8(c)(2)(i)(C) explaining that for a covered vending machine food with multiple servings a vending machine operator may voluntarily disclose calories per serving in addition to the total calories for the covered vending machine food. This sentence was originally included in § 101.8(c)(2)(i)(E). Because we have moved the sentence to § 101.8(c)(2)(i)(C) and § 101.8(c)(2)(i)(C) now applies to both single- and multiple-serving covered vending machine foods, we have removed proposed § 101.8(c)(2)(i)(E).

vi. *Calorie declarations on signs in close proximity to the article of food or selection button.*

Proposed § 101.8(c)(2)(ii) would establish requirements pertaining to the placement of calorie declarations. Proposed § 101.8(c)(2)(ii)(A) would require the calorie declarations to be placed on a sign in close proximity to the article of food or selection button, *i.e.,* in, on, or adjacent to the vending machine, but not necessarily attached to the vending machine, so long as the sign is visible at the same time as the food, its name, price, or selection button or selection number is visible.

The preamble to the proposed rule explained that ''a sign that is a poster may be an appropriate medium to convey the required calorie declarations, so long as the sign is in close proximity to the covered vending machine food or selection button'' (76 FR 19238 at 19243). We also tentatively concluded that for certain types of vending machines with a limited number of selections (*e.g.,* popcorn with or without added butter), the sign with the statement of calories may appear anywhere on the front (or face) of the vending machine, and that ''a sign may consist of a handwritten sticker in permanent marking that is affixed to the machine'' (76 FR 19238 at 19243).

(Comment 25) One comment asked that we permit a ''static cling'' type label (*e.g.,* a plastic decal that sticks to a surface because of static electricity) to be placed on the outside of ''closed-front'' vending machines (*i.e.,* vending machines that do not have transparent glass fronts).

(Response 25) Section 403(q)(5)(H)(viii) of the FD&C Act does not specify how a sign declaring calories is to be affixed to a vending machine or what materials are to be used for the sign. To give vending machine operators the greatest flexibility, the final rule also does not specify the type of material to be used as a sign or the manner in which the sign must be affixed to a vending machine. However, regardless of the material used for the sign, compliance with the calorie labeling requirements is contingent on the sign being in close proximity to each article of food or selection button and otherwise satisfying the requirements of section 403(a)(1), (f), and (q)(5)(H)(viii) of the FD&C Act and § 101.8.

(Comment 26) Many comments supported proposed § 101.8(c)(2)(ii)(A), which would allow a vending machine operator to provide a sign in close proximity to each article of food or selection button that displays calorie declarations for multiple vending machine foods. These comments stated that allowing vending machine operators to provide a sign with calorie declarations in this manner would be the least expensive and least burdensome way for vending machine operators to comply with section 403(q)(5)(H)(viii) of the FD&C Act. Some comments stated that a sign or poster could cost as little as $5 per vending machine and would be the ''least burdensome'' on small businesses. Other comments stated that allowing a vending machine operator to provide calorie declarations on a sign adjacent to or on the vending machine would reduce stocking errors by blind vending machine operators.

Conversely, some comments claimed that section 403(q)(5)(H)(viii) of the FD&C Act requires calorie declarations to be on individual ''signs'' for each article of food and that posting calorie declarations for multiple foods on a single sign that is not adjacent to the corresponding article of food would not meet the statute's requirements. One comment argued that if FDA permits calorie declarations for multiple vending machine foods on a single sign, we should at least prohibit such single signs from being placed adjacent to the vending machine, and ensure the close proximity of the single sign to each article of food or the selection button by revising the rule to read as follows: ''This calorie information must be placed on a sign next to the article of food or its selection button, or on a sign appended to the front of the vending machine at a similar height as the machine's selection buttons.''

(Response 26) Section 403(q)(5)(H)(viii) of the FD&C Act expressly states, in relevant part, that a vending machine operator must provide ''a sign in close proximity to each article of food or the selection button that includes the number of calories contained in the article.'' Section 403(q)(5)(H)(viii) of the FD&C Act does not specify whether vending machine operators must use a single sign with calorie declarations for multiple articles of food, or multiple signs corresponding to each article of food or selection button. To give vending machine operators the greatest amount of flexibility and to take into consideration different types of vending machines, we interpret section 403(q)(5)(H)(viii) of the FD&C Act to allow vending machine operators to use one sign with calorie declarations for all of the covered vending machine food sold from the vending machine or a sign for each covered vending machine food sold

from the vending machine, or a combination of the two, as long as the sign or signs are in close proximity to the covered vending machine food or selection button, as provided in § 101.8(c)(2), and otherwise satisfies the requirements of section 403(a)(1), (f), and (q)(5)(H)(viii) of the FD&C Act and § 101.8.

(Comment 27) Some comments asked us to clarify whether the rule would permit a vending machine operator to provide a sign adjacent to the vending machine that lists calorie declarations for all possible products that could be sold from the machine. The comments stated that such signs would be permanent in nature and would reduce the need to print new signs when different products are added to the vending machine.

Other comments suggested that grouping vending machine food items on a sign by category will allow consumers to better compare products.

(Response 27) We decline to revise § 101.8(c)(2)(ii)(A) to allow a vending machine operator to provide a sign adjacent to the vending machine that lists all possible articles of food that could be sold from the machine. However, we would not object to a vending machine operator providing calorie declarations for articles of food that are typically offered for sale in the specific vending machine but may not be offered for sale at all times (for example, in cases where the article sells out, or is temporarily replaced by another item), provided that the calorie declarations are clear and conspicuous and placed prominently. The calorie labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act apply ''[i]n the case of an article of food *sold* from a vending machine'' (emphasis added). Accordingly, whether a vending machine operator provides individual signs for each article of food or selection button, or a sign with calorie declarations for multiple articles of food, section 403(q)(5)(H)(viii) of the FD&C Act requires vending machine operators to provide clear and conspicuous calorie declarations for those articles of food that are sold from the machine. Vending machine operators must also ensure that such calorie declarations are not false or misleading as required by section 403(a)(1) of the FD&C Act and are prominently placed on signs with such conspicuousness and in such terms as to render the calorie declarations likely to be read and understood by the ordinary individual under customary conditions of purchase and use as required by section 403(f) of the FD&C Act. A long listing of food items, some of which are not available for sale in a vending machine, might make it more difficult for a prospective purchaser to locate the relevant calorie declarations for articles of food actually sold from the vending machine. In other words, depending on the number of foods listed on the sign and other factors, inclusion of calorie declarations for covered vending machine foods that are not sold from the particular vending machine, could result in the calorie declarations for covered vending machine foods actually sold from the vending machine no longer being clear and conspicuous, non-misleading, prominently placed and likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Therefore, we have revised § 101.8(c)(2)(ii)(A) to state that the list of covered vending machine food items on a sign must give calorie declarations for those articles of food that are sold from that particular vending machine.

At the same time, we recognize that calorie declarations could, in some cases, be displayed for vending machine foods that are not available for sale in the machine at a given time. For example, the food may have been offered for sale in the vending machine but the vending machine may have sold out of that item at some point in time. As another example, a food that is typically stocked in a vending machine might be temporarily replaced by another item. Nevertheless, vending machine operators must continue to ensure that calorie declarations on such a sign are tailored to articles of food currently or typically sold from that particular vending machine and otherwise satisfy the requirements of section 403(a)(1), (f), and (q)(5)(H)(viii) of the FD&C Act and § 101.8.

As for the comments suggesting that signs adjacent to the vending machines should group food items together, the final rule does not prescribe the manner in which articles of food and their associated calories are listed on a sign. Therefore, vending machine operators have the flexibility to organize the information on the signs as they wish, provided that the sign and the information on the sign comply with section 403(a)(1), (f), and (q)(5)(H)(viii) of the FD&C Act and § 101.8.

(Comment 28) Many comments opposed allowing vending machine operators to declare calories on a sign adjacent to the vending machine. Some comments contended that consumers are unlikely to see calorie declarations on a sign adjacent to a vending machine, particularly compared to calorie declarations posted directly next to each vending machine food, but did not provide any data to support this contention. One comment suggested that we require a statement on the vending machine directing the consumer to the location of the sign adjacent to the machine.

(Response 28) We disagree with those comments stating that we should not allow signs adjacent to the vending machine. Section 403(q)(5)(H)(viii) of the FD&C Act expressly states that ''a vending machine operator shall provide a sign in close proximity to each article of food or the selection button . . . .'' We have determined that a sign that is adjacent to the vending machine is ''in close proximity,'' to the covered vending machine food or selection button, so long as the calorie declaration on the sign is visible at the same time as the food, its name, or its selection button or selection number is visible.

We also note that § 101.8(c)(2)(ii) requires that the sign be ''placed prominently.'' To help ensure that calorie declarations on a sign placed adjacent to the vending machine are clear and conspicuous, and placed prominently, § 101.8(c)(2)(ii)(C) requires that the calorie declaration must be in type that is all black or one color printed on a white or other neutral background that contrasts with the type color. Further, § 101.8(c)(2)(ii)(C) also helps to ensure that such calorie declarations are prominently placed on signs with such conspicuousness and in such terms as to render them likely to be read and understood by the prospective purchaser under customary conditions of purchase and use, consistent with section 403(f) of the FD&C Act. Considering our interpretation of ''close proximity'' and the requirement of § 101.8(c)(2)(ii), we conclude that an additional statement directing the consumer to the sign is not necessary. Therefore, we decline to amend the rule to require a statement on the vending machine that directs the consumer to the location of a sign adjacent to the vending machine. However, to further address the comments' concern regarding the visibility of the calorie declarations on a sign adjacent to a vending machine, we have modified § 101.8(c)(2)(ii)(A) to specify that the *calorie declaration* must be visible at the same time as the food, its name, price, selection button, or selection number is visible (emphasis added). In addition, on our own initiative, we have replaced the reference to ''[t]his calorie information'' at the beginning of § 101.8(c)(2)(ii)(A) with ''the calorie declarations'' to be consistent with the rest of the final rule.

As discussed in response 20, we have also moved the requirement in the introductory sentence of proposed § 101.8(c)(2)(i) that the number of calories ''must be clear and conspicuous,'' and placed it instead in the introductory sentence of § 101.8(c)(2)(ii) for this final rule. The ''clear and conspicuous'' standard more appropriately reflects the requirements in § 101.8(c)(2)(ii), which focus on the placement and appearance of the calorie declarations, rather than the requirements of § 101.8(c)(2)(i), which focus on the content of the calorie declarations.

(Comment 29) One comment, opposed to allowing calorie declarations on signs adjacent to vending machines, compared such signs to stanchions at drive-through restaurants. The comment stated that, in the context of drive-through restaurants, FDA has already taken the position in its proposed rule for nutrition labeling of standard menu items in restaurants and similar retail food establishments (76 FR 19192) that requiring consumers to look to one place (*i.e.,* a menu board) for important food-selection information such as price and then to another (*e.g.,* a stanchion) for calories, ''is likely to be more difficult for customers attempting to use the declared calorie information at the point of selection'' (76 FR 19192 at 19206). The comment contended that it would be similarly difficult for consumers to use calorie information if consumers had to look at the food in the vending machine and at an adjacent sign for calorie declarations.

(Response 29) We disagree with the comment. Section 403(q)(5)(H)(ii)(II)(aa) of the FD&C Act requires, in relevant part, that a covered restaurant or similar retail food establishment disclose the number of calories in a standard menu item ''adjacent to the name of the standard menu item . . . *on the menu board, including a drive-through menu board* . . . .'' (emphasis added). Section 403(q)(5)(H)(viii) of the FD&C Act, in contrast, requires a covered vending machine operator to ''provide a sign in close proximity to each article of food or the selection button . . . .'' Thus, the placement of calorie declarations for covered vending machine food under section 403(q)(5)(H)(viii) of the FD&C Act is not directly analogous to the placement of calorie information for standard menu items under section 403(q)(5)(H)(ii)(II)(aa) of the FD&C Act.

Further, we do not consider vending machines to present a situation that is analogous to menu boards at drive-through restaurants or similar retail food establishments. A menu board at a drive-through is distinguishable because, as we discussed in the proposed rule for nutrition labeling of standard menu items in restaurants and similar retail food establishments (76 FR 19192 at 19206), customers have a restricted field of vision from their car windows while in a drive-through, and they may have a relatively short time to consider and review the menu board before ordering (76 FR 19192 at 19206). Vending machine consumers generally are not faced with similar restrictions. Accordingly, we interpret ''a sign in close proximity to each article of food or the selection button'' within the context of section 403(q)(5)(H)(viii) of the FD&C Act to mean adjacent to the vending machine in addition to in or on the vending machine.

(Comment 30) Another comment noted that some localities prohibit the use of signs without permits and described certain jurisdictions that would levy a $25 fine for not obtaining a permit. According to the comment, such ordinances could be problematic for vending machine operators who would prefer to use signs adjacent to the vending machine to meet the calorie declaration requirements of section 403(q)(5)(H)(viii) of the FD&C Act.

(Response 30) This final rule gives vending machine operators the flexibility to comply with the calorie labeling requirements for vending machine foods in a way that minimizes burdens and that does not conflict with local requirements described by the comment. For example, where a State or local requirement regulates use of particular types of signs (*e.g.,* large signs, free-standing signs), a vending machine operator could still comply with the requirements of section 403(q)(5)(H)(viii) of the FD&C Act by providing a sign in or on the vending machine (*e.g.,* using small individual signs or stickers). Alternatively, a vending machine operator could stock foods in a vending machine that permits a prospective purchaser to view the calories, serving size, and servings per container listed in the Nutrition Facts label on the foods, or in a reproduction of the Nutrition Facts label; or that otherwise provides visible nutrition information at the point of purchase, as provided in § 101.8(b).

vii. *Color and contrast for calorie declarations in or on the vending machine.*

Proposed § 101.8(c)(2)(ii)(B) would specify that when the calorie information is in or on the vending machine, the calorie declaration must be in the same color or a color at least as conspicuous as the color of the name or the price of the food or selection number.

We received no comments on this provision. However, on our own initiative, as discussed in response 21, we have moved what was proposed as § 101.8(c)(2)(i)(C) to § 101.8(c)(2)(ii)(B) of this final rule to eliminate a duplicate requirement on color and contrast for calorie declarations in or on the vending machine. Section 101.8(c)(2)(ii)(B) now specifies that when the calorie declaration is in or on the vending machine, the calorie declaration must be in a type size no smaller than the name of the food on the machine (not the label), selection number, or price of the food as displayed on the vending machine, whichever is smallest, with the same prominence, *i.e.,* the same color, or in a color at least as conspicuous, as the color of the name, if applicable, or price of the food or selection number, and the same contrasting background, or a background at least as contrasting as the background used for the item it is in closest proximity to, *i.e.,* name, selection number, or price of the food item as displayed on the machine.

viii. *Type size, color, and contrast for calorie declarations adjacent to the vending machine.*

When the calorie declaration is on a sign adjacent to the vending machine, proposed § 101.8(c)(2)(ii)(C) would require the calorie declaration to be in type that is ''all black or one color printed on a white or other neutral background that contrasts with the type color'' (76 FR 19238 at 19254). The preamble to the proposed rule explained that we were not proposing a minimum type size for the calorie declaration when it is on a sign adjacent to the vending machine (76 FR 19238 at 19243), and we invited comment on this issue.

(Comment 31) One comment asked that we establish additional requirements for size, type face, and color for the calorie declarations on the signs adjacent to the vending machine but the comment did not provide any specific suggestions.

(Response 31) Unlike calorie declarations in or on the vending machine, calorie declarations on signs adjacent to a vending machine are not accompanied, or otherwise surrounded by, pre-existing text or colors to which we could link the requirements. We note however that section 403(q)(5)(H)(viii) of the FD&C Act requires that calorie declarations be clear and conspicuous, and the requirement that the calorie declarations be clear and conspicuous also is codified in § 101.8(c)(2)(i). Further, section 403(f) of the FD&C Act requires, in relevant part, that any word,

statement, or other information required by or under the FD&C Act to appear in the labeling of food be prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Thus, we conclude that a calorie declaration on a sign adjacent to a vending machine must be in a type size large enough to render it likely to be read and understood by the prospective purchaser under customary conditions of purchase and use, and we have revised § 101.8(c)(2)(ii)(C) accordingly. In addition, as discussed in response 28, we have modified § 101.8(c)(2)(ii)(A) to specify that calorie declarations on signs adjacent to vending machines must be visible at the same time as the food, its name, price, selection button, or selection number is visible.

On our own initiative, we have revised § 101.8(c)(2)(ii)(C) to replace the reference to calorie ''information'' with calorie ''declaration'' to be consistent with the rest of the final rule.

ix. *Vending machines displaying a picture or other representation of food.*

Proposed § 101.8(c)(2)(ii)(D) would require that, where the vending machine only displays a vignette or name of the food item, the calorie information must be in close proximity to the vignette or name or in close proximity to the selection button (76 FR 19238 at 19254).

We received no comments on this provision. However, on our own initiative, we have revised § 101.8(c)(2)(ii)(D) by inserting the words ''picture or other representation'' in place of ''vignette'' for plain language purposes, and by replacing the reference to calorie ''information'' with calorie ''declaration'' to be consistent with the rest of the final rule.

x. *Electronic vending machines.*

Proposed § 101.8(c)(2)(ii)(E) would require that, for electronic vending machines (*e.g.,* machines with digital or electronic or liquid crystal display (LCD) displays), the calorie information may be displayed when the selection numbers are entered but before the selection is confirmed.

(Comment 32) Some comments supported proposed § 101.8(c)(2)(ii)(E) and stated that such electronic or LCD displays meet the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. One comment stated that some electronic displays allow the consumer to view the full Nutrition Facts Panel and rotate a virtual image of the product, or otherwise allow consumers to compare the Nutrition Facts of two products side by side.

Many comments opposed or would delete proposed § 101.8(c)(2)(ii)(E). Several comments noted that electronic displays would show calorie declarations for just one food item at a time. A few comments said that calorie declarations for all food items must be available to consumers at the same time before selection of an item so that consumers can compare calorie declarations for items simultaneously. Otherwise, the comments argued, consumers would have to keep track of the calorie declarations for each item until they made a final selection.

One comment said that care should be taken in using the term ''purchaser,'' which the comment considered to be the person paying for the item. The comment said that the purchaser could be at a different location from the ''user'' of the vending machine. For example, some vending machines allow a ''purchaser'' to pay for a vended item in one location while a ''user'' obtains the vended item in another location. This comment also suggested adding a new provision for clarity to read as follows: ''For vending machines retrofitted with digital or electronic or liquid crystal display (LCD) displays, the calorie information may be displayed at the user's request before the purchase is confirmed by entering a selection ID, selecting a product image, searching by name, or filtering product based on specific criteria.'' The comment did not explain why the new provision would focus on retrofitted vending machines.

(Response 32) We disagree with the comments asserting that electronic vending machines cannot meet the requirements of section 403(q)(5)(H)(viii) of the FD&C Act because electronic vending machines might be able to display calorie information for only one food item at a time. First, we note that electronic vending machines that provide calorie declarations in close proximity to vending machine foods or their selection buttons would comply with the calorie declaration requirements in section 403(q)(5)(H)(viii) of the FD&C Act, provided that such calorie declarations otherwise comply with section 403(a)(1) and (f) of the FD&C Act and § 101.8. Second, we understand that electronic vending machines have varying capabilities, and so to provide flexibility for vending machine operators to satisfy the requirements of section 403(q)(5)(H)(viii) of the FD&C Act, we are not requiring calorie declarations for electronic vending machines to be rendered simultaneously, although some electronic vending machines may have this capability. An electronic display that provides calorie declarations for one food at a time, allowing the prospective purchaser to cancel his or her initial selection, and then select other items in order to obtain the calorie declaration for each of them would constitute ''a sign in close proximity to each article of food or the selection button . . . disclosing the number of calories contained in the article,'' as required by section 403(q)(5)(H)(viii) of the FD&C Act. We therefore conclude that electronic vending machines may satisfy the calorie labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act.

However, to further ensure that the prospective purchaser is able to view the calorie declaration before making a purchase, we have revised § 101.8(c)(2)(ii)(E) on our own initiative to replace the proposed language with language stating that the calorie declaration must be displayed before the prospective purchaser makes his or her purchase.

As discussed in response 13, we also note that an electronic reproduction of the Nutrition Facts label could be one way that a vending machine could permit a prospective purchaser to examine the Nutrition Facts Panel for an article of food to satisfy section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act. Therefore, we have revised § 101.8(b)(2) by adding a new paragraph (b)(2)(ii) pertaining to electronic reproductions of the Nutrition Facts label.

We decline to adopt the comment's suggestion that we revise the final rule to distinguish between a vending machine ''user'' and ''purchaser.'' Section 403(q)(5)(H)(viii) of the FD&C Act uses the term ''prospective purchaser'' and does not make a distinction between a ''prospective purchaser'' and a vending machine ''user.'' Accordingly, we decline to make such a distinction in the final rule.

We also decline to adopt the comment's suggested language regarding ''retrofitted'' vending machines and the manner in which calorie information may be displayed. Section 403(q)(5)(H)(viii) of the FD&C Act does not address retrofitting of vending machines with digital, electronic, or other displays, and does not distinguish between retrofitted vending machines with such displays and other vending machines. We also note that the comment's suggested language, ''may be displayed at the user's request,'' would make the display of calorie information discretionary, and such a result would be inconsistent with the statutory requirement of section 403(q)(5)(H)(viii) of the FD&C Act that a covered vending machine operator provide a sign

disclosing the number of calories contained in a covered vending machine food.

xi. *Vending machines with limited choices.*

Proposed § 101.8(c)(2)(ii)(F) would provide that for vending machines with limited choices, such as vending machines that dispense only popcorn, the declaration of calories may appear on the face of the machine so long as the declaration is prominent, not crowded by other labeling on the machine, and the type size is reasonably related to the largest print on the vending machine.

We received no comments on this provision. However, as described in response 16 of this preamble, we revised § 101.8(b)(2)(i), in response to comments regarding type size and prominence of the visible nutrition information on the label of the food, to replace the words ''reasonably related'' with ''at least 50 percent of the size of the largest print on the label.'' For consistency with our edit to § 101.8(b)(2)(i) and to provide additional clarity, we are revising § 101.8(c)(2)(ii)(F). We considered whether to replace ''reasonably related to the largest print on the vending machine'' with ''at least 50 percent of the size of the largest print on the vending machine.'' However, we note that unlike § 101.8(b)(2)(i), where we are establishing a type size requirement based on other printed material on the label of a package of food, here we are establishing a type size requirement based on other printed material on the vending machine itself. Given the comparatively large surface area of vending machines, we are not requiring that the calorie declaration be 50 percent of the size of the largest print on the face of the vending machine, as the largest print could potentially be very large. Instead, § 101.8(c)(2)(ii)(F), as finalized, provides that for vending machines with limited choices, the declaration of calories may appear on the face of the machine so long as the declaration is prominent, not crowded by other labeling on the machine, and the type size is no smaller than the name of the food on the machine (not the label), selection number, or price of the food as displayed on the vending machine, whichever is smallest.

5. Voluntary Registration To Provide Calorie Labeling for Foods Sold From Vending Machines

Proposed § 101.8(d) would provide that a vending machine operator that is not subject to section 403(q)(5)(H)(viii) of the FD&C Act may voluntarily register with FDA to be subject to the calorie labeling requirements established in § 101.8(c)(2). Proposed § 101.8(d)(1) and (d)(2) would describe the applicability of the voluntary registration provision and who may register. Proposed § 101.8(d)(3)(i) through (d)(3)(iv) would list the information that a vending machine operator would be required to provide to FDA (*i.e.,* contact information for the vending machine operator, address of the location of each vending machine, preferred mailing address, certification of the information submitted) in order to register voluntarily. Proposed § 101.8(d)(3)(v) and (d)(3)(vi) also would describe the mechanism for submission of the information by email, fax, mail, or online form. Finally, proposed § 101.8(d)(3)(vii) would require re-registration every other year within 60 days prior to the expiration of the vending machine operator's current registration with FDA.

We received comments asking us to expand the voluntary database to require registration of all operators of covered vending machines, and we will address those comments in section III.C.6 of this preamble. We received no other comments on proposed § 101.8(d). However, on our own initiative, we have revised § 101.8(d) to clarify that the vending machine operator, rather than its authorized official, becomes subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act through voluntary registration, even if the authorized official voluntarily registered on the vending machine operator's behalf. Also, for completeness, we have added ''.gov'' to the end of the email address provided for voluntary registration under § 101.8(d). The complete email address now reads ''*menulawregistration@fda.hhs.gov*.''

6. Vending Machine Operator Contact Information

(Comment 33) Some comments said we should develop a database of covered vending machine operators and those who have elected to comply voluntarily with section 403(q)(5)(H)(viii) of the FD&C Act. The comments stated that the database could enable state and local inspectors to determine which vending machines are subject to the calorie declaration requirements of section 403(q)(5)(H)(viii) of the FD&C Act.

Another comment suggested that, to help with enforcement, we could expand the voluntary registry in § 101.8(d) to require all operators of covered vending machines to provide FDA with their names, contact information, and number and location of vending machines. The comment stated that we could share this information with States and localities that enforce local calorie labeling laws. As an alternative, the comment suggested that we require vending machine operators to post this information (name, contact information, etc.) on the front of each vending machine.

(Response 33) The final rule, at § 101.8(e)(1) and (e)(2), adds a requirement for vending machine operators to post their contact information for vending machines selling covered vending machine food. (We have renumbered proposed § 101.8(e), which dealt with the topic of signatures, as § 101.8(f) in the final rule). As indicated by a comment, such a requirement is necessary for efficient enforcement of section 403(q)(5)(H)(viii) of the FD&C Act because it enables FDA to contact vending machine operators for enforcement purposes. Without such a requirement, we would not be able to contact vending machine operators subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act because such contact information would not always be readily available to the Agency. Section 101.8(e)(1) specifies that the contact information must list the vending machine operator's name, telephone number, and mailing address or email address.

Section 101.8(e)(2) specifies that the contact information must be readable and may be placed on the face of the vending machine, or otherwise must be placed with the calorie declarations described in § 101.8(c)(2)(ii) (*i.e.,* on the sign in, on, or adjacent to the vending machine). We are providing flexibility to vending machine operators regarding where they can display the contact information. We note that some States have licensing requirements for vending machine operators, and some of these licensing requirements already require the vending machine operator's license or contact information to be displayed on the vending machine. If the contact information displayed on a vending machine due to State or local requirements includes some but not all of the contact information required under § 101.8(e)(1), the vending machine operator must display the remaining contact information required under § 101.8(e)(1) in the manner specified under § 101.8(e)(2). In other words, rather than requiring the vending machine operator to display contact information twice, we are providing flexibility by allowing vending machine operators to display the remaining contact information in a manner permitted in § 101.8(e)(2). For example, if a vending machine operator is required to display its name and address

on the face of a vending machine under an applicable State or local requirement and the operator complied with such requirement, the operator could display the remaining contact information required under § 101.8(e)(1) (*i.e.,* its phone number) on the face of the vending machine or on the sign listing calorie declarations in, on, or adjacent to the vending machine in order to comply with § 101.8(e). Regardless of the method that vending machine operators select to satisfy the requirements of § 101.8(e), they should ensure that the information being provided is their contact information.

As for the comments requesting that all vending machine operators (including those who are subject to section 403(q)(5)(H)(viii) of the FD&C Act and those who voluntarily register to be subject to section 403(q)(5)(H)(viii) of the FD&C Act) register with FDA, we decline to establish such a database at this time. We believe it would be more practical to wait until we and vending machine operators have been able to implement the vending machine labeling requirements and see what issues arise as part of that implementation.

7. Signatures

Proposed § 101.8(e) would provide that signatures obtained under the voluntary registration provisions that meet the definition of electronic signatures in § 11.3(b)(7) are exempt from the requirements of part 11.

The preamble to the proposed rule indicated that we expect this exemption for signatures to facilitate the voluntary registration process (76 FR 19238 at 19245).

We received no comments on this provision, however because we have added a new § 101.8(e) (contact information of vending machine operators for vending machines selling covered vending machine food), we have renumbered this provision as § 101.8(f).

D. Determination of Calorie Content

Section 403(q)(5)(H)(viii) of the FD&C Act does not prescribe where or how covered vending machine operators must obtain the necessary calorie information to meet the calorie declaration requirements for covered vending machine foods. If a covered vending machine food does not bear Nutrition Facts, we anticipated in the preamble to the proposed rule, that the vending machine operator could obtain the calorie information from food manufacturers or suppliers (76 FR 19238 at 19242). We invited comment on whether ''a vending machine operator may use nutrient databases, cookbooks, laboratory analyses, and other reasonable means'' if calorie information is not available from the food manufacturer or supplier (Id.). We also invited comment on ''whether vending machine operators should be required to provide FDA the information on which they relied to determine the total calories posted for the vending machine food'' (76 FR 19238 at 19242).

(Comment 34) One comment supported allowing covered vending machine operators to use nutrient databases and cookbooks as tools for determining calorie information if calorie information is not available from the food manufacturer or supplier. The comment also suggested allowing menus as a tool for determining calorie information. Further, the comment said that we should not require vending machine operators to give FDA the method or information on which the vending machine operators relied to determine the total calories posted for the vending machine food. The comment said that such a requirement would be an economic burden both for the vending machine operator to provide such information and for FDA to collect, record, and store such information. Another comment suggested that FDA require covered vending machine operators to have a reasonable basis for calorie declarations for vending machine foods, in accordance with the reasonable basis provision for nutrition labeling for standard menu items offered for sale in restaurants and similar retail food establishments in section 403(q)(5)(H)(iv) of the FD&C Act.

(Response 34) We agree with the comments supporting the use of nutrient databases and cookbooks to determine the total calories contained in a covered vending machine food. A vending machine operator may obtain the necessary calorie information from the food package's Nutrition Facts label, the manufacturer or supplier of the food, nutrient databases, cookbooks, or laboratory analyses. We anticipate that, for most packaged foods, the vending machine operator will use the food package's Nutrition Facts label to determine calorie information for the food.

Menus likely would not be a reliable means of determining the calorie information for a vending machine food, because the ingredients, portion size, and method of preparing a food listed on a menu may differ from those used for a food sold from a vending machine. Such differences may result in a calorie declaration for a food listed on a menu that does not accurately reflect the calorie content of the same food sold from a vending machine. We recognize, however, that compliance ultimately is based on the accuracy of the declaration rather than just the method used to determine the calorie information.

We anticipate that vending machine operators are likely to generate and maintain a record of the information on which they relied to determine the total calories posted for the vending machine food. We encourage vending machine operators to be prepared to share it with FDA upon our request during an inspection if we need to determine whether the calories declarations, posted by a vending machine operator under § 101.8(c), are truthful and not misleading.

We disagree with the comment suggesting that we apply the reasonable basis provision in section 403(q)(5)(H)(vi) of the FD&C Act to covered vending machine food. The reasonable basis requirement in section 403(q)(5)(H)(vi) of the FD&C Act applies only to restaurants and similar retail food establishments covered by the requirements of section 403(q)(5)(H) of the FD&C Act, and does not apply to covered vending machine food. We note that covered vending machine operators must ensure that calorie declarations are truthful and not misleading under section 403(a)(1) of the FD&C Act, and otherwise comply with section 403(q)(5)(H)(viii) and (f) of the FD&C Act and § 101.8.

E. Effective Date

The preamble to the proposed rule indicated that a final rule would become effective 1 year from the date of publication of the final rule in the **Federal Register** (76 FR 19238 at 19245).

(Comment 35) Many comments suggested that FDA make the final rule effective 6 months after its publication. Noting that we proposed a 6-month effective date in the proposed rule pertaining to nutrition labeling of standard menu items in restaurants and similar retail food establishments, the comments argued that labeling foods sold in vending machines with calorie information would be even less burdensome than restaurant menu labeling because a vending machine operator could simply post stickers listing calories to meet the requirements. The comments asserted that vending machine operators should be able to comply with the calorie labeling requirements within the same timeframe that we proposed in the proposed rule for nutrition labeling of standard menu items in restaurants and

similar retail food establishments (76 FR 19192).

Other comments—many from vending machine trade associations—requested a minimum of 2 years to come into compliance. The comments claimed that 1 year was not sufficient time to come into compliance because more than 70 percent of vending machine operators have three or fewer employees. Some comments said that because vending machine operators may have few employees, placing calorie declarations for all of their vending machines would be costly and time-consuming.

A few comments asserted that a 2-year effective date is needed due to a lengthy design and test process for new vending machines, and to establish a relationship between vending machine operators and food manufacturers in order to develop ''verification procedures'' which typically do not exist at the present time. The comments did not explain what they meant by ''verification procedures.''

Another comment suggested a phased-in implementation period to give vending machine operators a longer time to meet the calorie declaration requirements. The comment did not state how long the phased-in implementation period should be.

A few comments said we should follow the same approach that we have taken historically for other food labeling changes and cited FDA's uniform compliance date policy for food labeling regulations. The comments stated that the uniform compliance date for food labeling regulations issued between January 1, 2011, and December 31, 2012, is January 1, 2014 (75 FR 78155 (December 15, 2010)), and we should, therefore, impose an effective date of January 1, 2014, assuming the final rule publishes before December 31, 2012.

(Response 35) We recognize that vending machine operators may have few employees and resources. We also understand that vending machine manufacturers and food manufacturers are continuing to design new products, and that vending machine operators may wish to work with vending machine manufacturers and food manufacturers to develop ways to comply with section 403(q)(5)(H)(viii) of the FD&C Act. We are also taking into consideration FDA's 2012 final rule (77 FR 70885, November 28, 2012), which establishes January 1, 2016, as the next uniform compliance date for food labeling changes required by food labeling regulations that are issued between January 1, 2013, and December 31, 2014. Because vending machine operators may display the Nutrition Facts label or other visible nutrition information in order to satisfy § 101.8(b), it would be helpful for vending machine operators to see any changes that manufacturers may make to the labels of packaged foods which may be timed in accordance with the next uniform compliance date. For these reasons, we are revising the effective date of the final rule to 2 years from the date of its publication in the **Federal Register**, which will be after the January 1, 2016 uniform compliance date. All covered vending machine operators must come into compliance with the requirements of this rule no later than 2 years after the date of its publication.

F. Enforcement

(Comment 36) Some comments said we should devise a reporting mechanism for individuals to report possible violations of section 403(q)(5)(H)(viii) of the FD&C Act and a regime of penalties for confirmed violations. These comments also suggested that we develop a protocol for checking the accuracy of the calorie information provided by covered vending machine operators.

(Response 36) We decline to establish a reporting mechanism for individuals to report possible violations of section 403(q)(5)(H)(viii) of the FD&C Act or the final rule. FDA's regulations already provide individuals with mechanisms to communicate with the Agency. If an individual finds that the calorie declaration for an article of food sold from a vending machine is incorrect, he or she can contact FDA by calling the FDA complaint coordinator for their region (*http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm*).

As for the comments' suggestion regarding penalties, penalties are already set forth in the FD&C Act. We are establishing these regulations under sections 201(n), 403(a)(1), (f), (q)(5)(H), and 701(a) of the FD&C Act. Therefore, we note that failure to comply with the regulations will render the covered vending machine food misbranded under section 403(a), (f), or (q) of the FD&C Act. Violations of § 101.8 may result in enforcement action. For example, introducing, delivering for introduction, or receiving a misbranded food in or into interstate commerce, or misbranding a food while it is in interstate commerce or being held for sale after shipment in interstate commerce, are prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331), carrying criminal penalties under section 303 of the FD&C Act (21 U.S.C. 333). In addition, under section 302 of the FD&C Act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 304(a)(1) of the FD&C Act (21 U.S.C. 334(a)(1)), food that is misbranded when introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce may be seized by order of a Federal court.

With respect to the comments suggesting that we develop a protocol to check the accuracy of calorie information, we intend to develop an enforcement strategy as we gain more experience with the final rule. For example, we could first check to ensure that the calorie declaration provided by a covered vending machine operator matches the calorie information on the article of food from the food manufacturer or supplier, such as on the Nutrition Facts label. We could also use lab analyses to determine whether the calorie declaration for a given vending machine food is accurate.

(Comment 37) Another comment asked us to provide training, guidance, and funding to State and local inspectors to facilitate enforcement.

(Response 37) The final rule does not become effective until December 1, 2016. During that period we will assess resources and consider conducting training or further outreach as necessary.

IV. Analysis of Impacts—Final Regulatory Impact Analysis

FDA has examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a detailed Regulatory Impact Analysis (RIA) that presents the benefits and costs of this final rule (Ref. 1) which is available at *http://www.regulations.gov* (enter Docket No. FDA–2011–F–0171). The full economic impact analyses of FDA regulations are no longer (as of April 2012) published in the **Federal Register** but are submitted to the docket and are available at *http://www.regulations.gov.* We also post the full economic impact analyses of FDA regulations at the following Web site: *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

We believe that the final rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. According to our analysis, we believe that the final rule will have a significant economic impact on a substantial number of small entities, and we have accordingly analyzed regulatory options that would minimize the economic impact of the rule on small entities consistent with statutory objectives. We have crafted the final rule to provide flexibility for compliance.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The analyses that we have performed to examine the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995 are included in the RIA (Ref. 1).

We had prepared a ''Preliminary Regulatory Impact Analysis'' (Ref. 2) in connection with the proposed rule. We also included sections titled ''Summary Preliminary Regulatory Impact Analysis'' and ''Initial Regulatory Flexibility Analysis'' in the preamble to the proposed rule (76 FR 19238 at 19245–19249). We received comments on our analysis of the impacts presented in those sections, and the RIA (Ref. 1) contains our responses to those comments.

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given in this section of the document with estimates of the annual reporting and third-party disclosure burden. Included in each burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We had included a section entitled ''Paperwork Reduction Act'' in the preamble to the proposed rule (76 FR 19238 at 19249–19251). We received the following comments on our analysis of the burdens presented in the proposed rule.

(Comment 38) One comment stated that we did not calculate the burdens to the suppliers of vending machine food. The comment stated that these suppliers will bear the larger burden from the requirements of the final rule.

(Response 38) Neither section 403(q)(5)(H)(viii) of the FD&C Act nor the final rule applies to suppliers of vending machine food; instead, section 403(q)(5)(H)(viii) of the FD&C Act and the final rule establish requirements for certain vending machine operators. We recognize that a supplier of covered vending machine food may provide calorie information on front-of-package labeling and such calorie information may constitute visible nutrition information in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act provided that the applicable requirements of § 101.8(b) are satisfied. However, neither section 403(q)(5)(H)(viii) of the FD&C Act nor the final rule requires suppliers to provide such information. As such, the final rule does not impose burdens on suppliers of vending machine food.

(Comment 39) One comment stated that posting calories would not be burdensome, as most foods sold in vending machines already provide calorie information on their Nutrition Facts labels, and for foods that do not already have calorie information, labeling to disclose calories can be accomplished easily by using stickers. Another comment stated that, in light of the major beverage companies' prior commitment to putting calorie information on selection buttons, we should reduce our burden estimate.

(Response 39) To the extent that foods sold from covered vending machines permit a prospective purchaser to examine the Nutrition Facts label before purchasing the food or otherwise provide visible nutrition information at the point of purchase in accordance with section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8(b), the vending machine operator would not be required to provide calorie declarations for such foods. In addition, we recognize that the ''Clear on Calories'' commitment by the American Beverage Association, which includes a pledge that calories will be displayed on selection buttons of ''company-controlled vending machines,'' may be consistent with the calorie declaration requirements of section 403(q)(5)(H)(viii) of the FD&C Act. Our estimates of the burdens already account for the fact that many vending machine foods will not require additional nutrition analysis under this final rule. For example, we estimate in the RIA that only 723 to 963 covered vending machine operators will need to acquire nutrition information for at least some of their vending machine food (Ref. 1).

Our estimate of the burdens and cost of nutrition analysis also takes into consideration that vending machine operators can comply with the requirements of the final rule by providing calorie declarations through less burdensome and less expensive means (*e.g.,* a poster affixed to the front of the machine could cost, on average, $20 per machine per year) (Ref. 1). The final rule does not prescribe the types of materials through which calories must be declared, and a sticker, for example, could be an appropriate medium to convey a required calorie declaration.

(Comment 40) One comment stated that our estimate on how frequently labeling would need to change is too low. The comment stated that in almost all cases, machines are restocked and serviced every 5 weeks, with busier locations stocked once or more per week. The comment stated that the restocking will require labeling changes because restocking may result in the substitution of certain products for other products or the addition of new products. The comment stated that relabeling would need to occur between 10 and 17 times per year for each machine, with some machines requiring partial relabeling at least 50 times per year.

(Response 40) In the preliminary RIA, we estimated an average recurring burden of between 5 and 15 minutes per vending machine per year to install or refresh the calorie displays. We said that signs would not always need to be updated every time a machine's product mix (*i.e.,* the assortment of vending machine foods offered for sale in a vending machine at a particular time) changed.

We recognize that the product mix in a particular vending machine may change with each restocking. For each machine, the rule requires operators to declare the calorie information for those articles of food that are sold from that particular vending machine. However, we would not object to a vending machine operator providing calorie

declarations for articles of food that are typically offered for sale in a vending machine but may not be offered for sale at all times (for example, in cases where the article sells out, or is temporarily replaced by another item), provided that the calorie declarations are clear and conspicuous and placed prominently. Thus, signs would not always need to be updated every time a machine's product mix changed, so long as the sign declares the calories for each article of food sold from the covered vending machine. For example, if a particular article of food is sold out, the vending machine operator would not need to design and print a new sign to remove the calorie declaration for such food. In addition, to the extent that foods sold from covered vending machines permit a prospective purchaser to examine the Nutrition Facts label before purchasing the food or otherwise provide visible nutrition information at the point of purchase in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act and § 101.8(b), the vending machine operator would not be required to provide calorie declarations for such foods. Therefore, restocking of covered vending machines that sell such foods would not require the vending machine operator to update signs. Furthermore, in order to accommodate the occasional trial or experimental product, the sign template could, for example, be designed with blank space, on which the operator could handwrite the experimental product's name and caloric value, or place a declarative sticker next to the new product within the machine (should it have a glass/plexiglass front). The comment provided an estimate of the number of times a vending machine's sign would likely need to be replaced, or 10 to 17 times. We estimate that in accordance to the factors described in the earlier paragraphs of this response, calorie declaration signs would only need to be replaced between 1 and 4 times per year (or even zero for some products). This estimate also takes into consideration that vending machine operators have the flexibility to choose a medium (*e.g.,* stickers, posters) and a format (*e.g.,* individual signs per covered vending machine food; sign(s) in, on, or adjacent to the vending machine) for the calorie declaration that will make the most sense for a particular vending machine operator depending on the variability of products that the operator carries and the frequency of restocking.

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Information Collection Provisions of the Final Rule on Food Labeling; Calorie Labeling of Articles of Food in Vending Machines

A. Reporting Requirements

Description of Respondents

The likely respondents to this information collection are vending machine operators that voluntarily elect to be subject to the Federal requirements of this rule by registering with FDA.

Description

Vending machine operators not subject to the requirements of the ACA may elect to be subject to the Federal requirements by registering with FDA. Vending machine operators that voluntarily register must provide FDA with their contact information, the address of the location of each vending machine owned or operated by the vending machine operator that is being registered, the preferred mailing address (if different from the vending machine operator address) for purposes of receiving correspondence, and certification that the information submitted is true and accurate, that the person or firm submitting it is authorized to do so, and that each registered vending machine will be subject to the requirements of § 101.8. In the proposed rule, the total reporting burden included both the reporting burden for menu labeling and vending machine operator voluntary registration (see 76 FR 19238 and 19251). For the final rule, these burdens are estimated separately for each rule. To keep the establishment's registration active, the authorized official of the vending machine operator must register every other year within 60 days prior to the expiration of the vending machine operator's current registration with FDA. Registration will automatically expire if not renewed.

Vending machine operators that have voluntarily registered to become subject to the Federal requirements must satisfy the calorie labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8(c). We further note that an article of food sold from a vending machine operator who has voluntarily registered with FDA to be subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act is not required to provide calorie declarations for articles of food sold from a vending machine that permits the prospective purchaser to examine the Nutrition Facts label before purchasing the article as provided in § 101.8(b)(1), or otherwise provides visible nutrition information at the point of purchase as provided in § 101.8(b)(2).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN: VOLUNTARY REGISTRATION [1]

21 CFR part 101	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Initial Burden (annualized over 3 years):					
§ 101.8(d) Initial Registration	13	1	13	2	26
Annual Burden:					
§ 101.8(d) Registration Renewal	19	1	19	[2] 0.5	9.5
Total Burden Hours					35.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 30 minutes.

We lack data on the number of vending machine operators with fewer than 20 machines that might voluntarily register to comply with this final rule. We do not expect the net benefit for voluntary registration by any non-covered vending machine operators to be positive and in the RIA (Ref. 1) we indicate that as of the conducting of this analysis, no vending machine operators have voluntarily registered with FDA. Therefore we did not estimate a significant burden in the RIA (Ref. 1). However, in the event that a few will register anyway, or find some positive incentive to do so, for the purposes of this PRA analysis, we estimate the burden such operators will face. We estimate there are approximately 757 vending machine operators with fewer than 20 machines; this number is based on the mean estimate of the low and high counts of firms with less than $50,000 in annual revenue from the RIA (Ref. 1). We estimate that 5 percent of vending machine operators with fewer than 20 machines may voluntarily register to become subject to the final requirements, or 38 operators. We estimate a burden of approximately 2 hours per initial registration, which yields a total burden of 76 hours (38 total operators × 2 hours per response). Annualizing this number over 3 years yields a rounded 13 respondents per year (5 percent × 757 operators/3 years). With an annualized estimate of 13 vending machine operators and one registration per vending machine operator at 2 hours per registration, we estimate the initial hourly burden for these operators is 26 hours.

We expect that renewal registrations after the first year will require substantially less time because operators are expected to be able to affirm or update the existing information in an online account in a way similar to other FDA firm registration systems. Therefore, we estimate that re-registration will take 0.5 hours for each registrant. This would indicate that biennial registration would impose a burden of 19 hours (38 operators × 0.5 hours) every 2 years, or 9.5 hours every year (18 operators every year × 0.5 hours).

B. Recordkeeping Requirements

The preamble to the proposed rule (76 FR 19238 at 19249–19251) provided an estimate of the recordkeeping burden, which consisted of the burden associated with calorie analysis and the burden associated with generating, providing, or maintaining records. Upon further consideration, we have omitted the burden estimate associated with generating, providing, or maintaining records previously provided in table 3 of the proposed rule because the rule does not require vending machine operators to generate, provide, or maintain records. Further, as discussed in section C of this analysis, we have included a burden estimate for calorie analysis as part of the third party disclosure burden, since the ''total time, effort, or financial resources expended by [covered vending machine operators]'' (5 CFR 1320.3(b)) to declare calories for covered vending machine food likely includes time, effort, or financial resources to determine the calorie content of such food.

C. Third-Party Disclosure Requirements

Description of Respondents

The likely respondents to this information collection are vending machine operators that are subject to the ACA's requirements and those that choose to voluntarily register to comply with the disclosure requirements.

Description

We calculate two types of third party disclosure burdens under the rule. The first burden is the time and effort expended by vending machine operators to determine the calorie content of covered vending machine food for the required calorie declarations, which we refer to as ''Calorie Analysis.''

Vending machine operators must also provide calorie declarations for covered vending machine foods on signs in, on, or adjacent to vending machines. The second burden is the cost of materials and the time expended by vending machine operators to physically produce and install the signs for the calorie declarations, which we refer to as ''Calorie Declaration Signs.'' We estimate the burden of signage for non-bulk and bulk vending machines separately. We provide our estimates of the third party disclosure burdens in table 2.

TABLE 2—THIRD PARTY DISCLOSURE BURDEN

21 CFR part 101	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours	Capital costs
§ 101.8(c)(2)(i), Calorie Analysis	282	11	3,102	1	3,102	
§ 101.8(c)(2)(ii), Template Design	3,279	5	16,395	2	32,790	
§ 101.8(c)(2)(ii), Sign Creation	3,279	125	409,875	0.475 (28.5 min.)	194,710	$4,671,047
§ 101.8(e)(1), Contact Information	3,279	125	409,875	0.025 (1.5 min.)	10,248	
§ 101.8(c)(2)(ii), Sign Installation	1,868,419	1	1,868,419	0.083 (5 min.)	155,079	
§ 101.8(c)(2)(ii), Sign Information Update.	511,576	2	1,023,152	0.5 (30 min.)	511,576	
§ 101.8(c)(2)(ii), Sign Replacement	1,755,986	2	3,511,972	0.17 (10 min.)	597,035	
§ 101.8(c)(2)(ii), Bulk Machine Signage.	128,533	1	128,533	0.025 (1.5 min.)	3,213	
Total Burden					1,507,753	4,671,047

Third-Party Disclosure Requirements: Calorie Analysis

A calorie analysis entails the burden of determining calorie content for covered vending machine food. Most foods sold from vending machines provide the nutrition labeling required by section 403(q) of the FD&C Act and § 101.9, including calorie content information, which means that calorie content for many covered vending machine foods is already available on the Nutrition Facts labels for such foods. In that case, vending machine operators will not need to determine the calorie content of such foods because they can simply declare the calorie information they find on the Nutrition Facts label. Nevertheless, some operators may need to determine calorie information for those vending machine foods that may not bear Nutrition Facts labels or otherwise provide visible nutrition information at the point of purchase in

accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act and § 101.8(b). An operator may obtain the necessary calorie information from nutrient databases, cookbooks, or laboratory analyses. Calorie analysis will most likely only be needed for vended food items such as refrigerated, frozen, can/bowl, or other shelf-stable main meal items, hot cup beverages, and cold cup beverages. We anticipate that vending machine operators are likely to generate and maintain a record of the information on which they relied to determine the total calories posted for the vending machine food.

As stated in the RIA (Ref. 1), we estimate the mean number of vending machine operators that need calorie analysis to be 847. Annualizing this estimate over 3 years yields 282 operators. We also estimate the range of products available in a typical machine for each of the three most commonly sold product categories that are likely to require a calorie analysis, or 3 percent of food items, 5 percent of hot beverages, and 1 percent of cold cup beverages. We estimate that food machines typically offer between 10 and 25 different items, and both hot beverage and cold cup beverage machines typically offer between 5 and 10 items. From this, we estimate each vending machine operator will require a calorie analysis for 11 items, on average. These estimates were based upon conversations with vending machine operators (Ref. 3) and our survey of various vending machine models that vend these types of food and beverage (Ref. 4). Based on data from FDA's Recordkeeping Cost Model (Ref. 5), we estimate the time needed to determine the calorie content of each covered vending machine food to be approximately 1 hour. Our estimate for the burden hours that would be required for new calorie analysis is then 9,317 hours (847 operators × 11 products needing analysis × 1 hour per analysis). Annualizing this value over 3 years yields 3,102 hours (847 operators/3 years × 11 products needing analysis × 4 hours per analysis). (847 operators/3 years = 282 operators per year.) There will not be capital costs associated with a calorie analysis.

Third-Party Disclosure Requirements: Calorie Declaration Signs

Under this rule, covered vending machine operators with 20 or more vending machines and vending machine operators that voluntarily register to become subject to the Federal requirements, must disclose calorie information by providing calorie declaration signs in, on, or adjacent to their vending machines to a third party who will most often be the prospective purchaser or consumer. Our burden estimate for the calorie declaration signs is based on the total time it takes for vending machine operators to produce and install the calorie declaration signs. We separately estimate the burden for two kinds of vending machines, non-bulk and bulk machines. For non-bulk vending machines, we estimate the burden to operators as the initial time it takes them to develop the calorie disclosure signage, which includes the time for the sign template design (*i.e.* the creation of generalized sign templates), sign creation (*i.e.* using templates to design machine-specific signs), and installation; and then the time for the recurring burden, which includes the time to update or change calorie information and the physical replacement of the disclosure signage when the product mix of the machine changes. For bulk machines, we estimate the burden to operators for the cost of individual calorie labels. (We assume that individual calorie declaration stickers will be placed on the face of each individual bulk vending machine, since each machine only vends a single product.) Recurring updates to signage will only likely be required for non-bulk, non-beverage machines since the product mixes of these machines are changed regularly, while the product mix for bulk machines is unlikely to change.

We estimate there is an average of 9,838 (9,800 covered non-bulk + 38 voluntary) vending machine operators subject to the rule. (9,838/3 = 3,279 annualized). Our estimate for the average number of non-bulk vending machines that will require declaration signage is based upon data obtained from the Vending Times Survey and National Automatic Merchandising Association (NAMA) and the Economic Census, and as summarized in table 8 of the final RIA (Refs. 1, 6 to 8). We estimate there is an average of 5.61 million non-bulk vending machines. Digital signage is an emerging technology, and according to NAMA approximately 0.1 percent of all vending machines in operation currently have electronic video displays capable of providing calorie information, or approximately 4,014 to 5,670 vending machines (Ref. 3). Subtracting the number of vending machines with the electronic video from the total machine count yields an average of 5.611 million vending machines that will need signage. We expect the number of vending machines that will require signage to decline over time as manufacturers continue to add the required calorie information to the principal display panel of the package as part of ''front of package labeling,'' and because we anticipate greater use of electronic video displays on vending machines. In addition, to the extent that covered vending machines sell foods that permit prospective purchasers to examine the Nutrition Facts label before purchase or otherwise provide visible nutrition information at the point of purchase in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act and § 101.8(b), this analysis may overestimate the burden estimate for calorie declaration signs.

We estimate the time it takes for the one-time design of a calorie disclosure sign template to be 2 hours. The number of templates a given firm would need to design to produce signs that comply with the rule may vary based upon the number of different types of products the firm purveys. We estimate a range of one to ten templates would be necessary. We base this range on the eight general food and beverage vending categories monitored by the Vending Times Census, plus two additional templates to account for the existence of combination machines, which vend more than one general product type (*e.g.* snacks and cold canned beverages)—see table 4 of the final RIA (Refs. 1, 6). Since not all firms will sell items from each of the general food categories, we estimate that on average, firms will sell items from approximately four general food categories and operate one set of combination machines, requiring the need to develop (on average) five templates. At 2 hours per template, the total initial burden for designing templates comes to an estimated 98,380 hours (9,838 operators × 5 templates × 2 hours per template). Annualizing this value over 3 years yields a burden of 32,790 hours (9,838 operators/3 years × 5 templates × 2 hours per template). There are no capital costs associated with template design.

We estimate the time it takes to enter calorie information into a single sign template and prepare it for printing to be 0.475 hours. Again, we estimate the number of machine configurations to be 125. The count of machine configurations is a general estimate of the number of different types of machines an operator uses to sell its products, and takes into account that fact that a machine's specific product mix will depend on locational characteristics (*e.g.* office vs. hotel) and the type of machine (*e.g.* beverage vs. snack). We estimate the total initial burden for sign creation using the predesigned templates to be 584,131

hours (9,838 operators × 125 sign formats × 0.475 hours per sign). Annualized over 3 years, this burden becomes 194,710 hours (9,838 operators/3 years × 125 signs × 0.475 hours per sign). Capital costs associated with sign creation correspond to the cost of paper and ink for printing the signs. As estimated in the RIA (Ref. 1), the capital costs are $2.50 per sign, which results in a total capital cost of $14,013,143 [(5,604,914 covered non-bulk machines + 343 voluntarily registered machines) × $2.50 per machine]. Annualized over 3 years, this value becomes $4,671,048 (5,605,257 machines/3 years × $2.50 per machine).

Vending machine operators must also provide their contact information on each vending machine selling covered vending machine food as required under § 101.8(e)(1). We assume that venders that do not already have a sign or label with their contact information will add their contact information into the initial sign design. We estimate the time it takes to include contact information is 1.5 minutes (0.025 hours) for each sign. We estimate the total initial burden for including contact information on the predesigned templates to be 30,744 hours (9,838 operators × 125 sign formats × 0.025 hours per sign). Annualized over 3 years, this burden becomes 10,248 hours (9,838 operators/3 years × 125 signs × 0.025 hours per sign). There are no capital costs associated with adding contact information. (Some States have licensing requirements for vending machine operators, and some of these licensing requirements already require the vending machine operator's license or contact information to be displayed on the vending machine. If the contact information displayed on a vending machine due to State or local requirements includes some but not all of the contact information required under § 101.8(e)(1), the vending machine operator is required to display the remaining contact information required under § 101.8(e)(1) in a manner specified under § 101.8(e)(1). We do not have an estimate of the number of machines already in compliance; to the extent that some operators are already in compliance, we overestimate the burden of third-party disclosure.)

We estimate the time it takes to install a sign onto a single machine to be 5 minutes (0.083 hours) for each sign. With 5,605,257 machines (5,604,914 covered machines + 343 voluntarily registered machines), we estimate the annual burden for initial sign installation to be 465,236 hours (5,605,257 machines × 1 sign per machine × 0.083 hours installation). Annualized over 3 years, this burden becomes 155,079 hours (5,605,257 machines/3 years × 1 sign per machine × 0.083 hours installation). (5,605,257 machines/3 years = 1,868,419 machines per year.) There are no capital costs associated with sign installation.

We divide the estimates for the recurring burden of non-bulk third-party disclosure into two parts: Updating calorie sign information for changes in the product mix (which involves updating the digital format) and physical sign replacement (which involves printing and installation). We estimate the average number of product configurations for machines that will experience regular changes to their product mix to be 52. This value is lower than the overall average of 125 since some machines (such as beverage machines) do not experience regular changes to the product mix. We estimate the average number of times that calorie signs will need to be updated to be twice per year. Finally, we estimate the time it takes to update a single sign using the predesigned template to be 0.5 hours. Thus, the total burden for updating sign information is 511,576 hours [511,576 records (made up of 9,838 operators × 52 product configurations) × 2 updates per year × 0.5 hours per update].

We estimate the annual number of covered machines that will need regular sign replacement to be 1,755,986 machines (1,755,879 covered machines + 107 voluntarily registered machines). We estimate the time it takes to remove and replace old signs with new signs to be 0.17 hours (10 minutes). Thus, the total annual burden for replacing signs is 597,035 hours (1,755,986 machines × 2 replacements per year × 0.17 hours per replacement). There are no capital costs associated with updating sign information or physical sign replacement.

We estimate there is an average of 385,600 covered bulk vending machines, based on data obtained from the Vending Times Census and NAMA (Refs. 6, 8). We assume each bulk machine vends a single bulk product, and we further assume they will choose the most economical signage, which means they are likely to use a small sticker on the face of each machine. We estimate the time to print and apply each sticker is 1.5 minutes (0.025 hours). Thus, the total burden for bulk machine signage is 9,640 hours (385,600 bulk machines × 0.025 hours per machine). Annualized over 3 years, this value becomes 3,213 hours (385,600/3 years × 0.025 hours per machine). (385,600/3 years) = 128,533 machines per year.)

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Information Collection Provisions of the Final Rule on Food Labeling; Calorie Labeling of Articles of Food in Vending Machines.''

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have resubmitted the information collection provisions of this final rule to OMB for review, because the final rule provides an additional modification to § 101.8. These requirements will not be effective until we obtain OMB approval. Interested persons are requested to submit comments regarding information collection to OMB (see **DATES** and **ADDRESSES**).

Prior to the effective and compliance date of this final rule, we will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision that preempts ''any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) [of the FD&C Act [21 U.S.C. 343(q)]]'', except that this provision does not apply ''to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment complies with the

voluntary provision of nutrition information requirements under section 403(q)(5)(H)(ix) [of the FD&C Act]'' (21 U.S.C. 343(q)(5)(H)(ix)). The final rule creates requirements for nutrition labeling of food under section 403(q) of the FD&C Act that would preempt certain non-identical State and local nutrition labeling requirements.

Section 4205 of the ACA also included a Rule of Construction providing that nothing in the amendments made by [section 4205] shall be construed—(1) to preempt any provision of State or local law, unless such provision establishes or continues into effect nutrient content disclosures of the type required under section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)(5)(H)] (as added by subsection(b)) and is expressly preempted under subsection (a)(4) of such section; (2) to apply to any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food; or (3) except as provided in section 403(q)(5)(H)(ix) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)(5)(H)(ix)] (as added by subsection (b)), to apply to any restaurant or similar retail food establishment other than a restaurant or similar retail food establishment described in section 403(q)(5)(H)(i) of such Act [21 U.S.C. 343(q)(5)(H)(i)]. (See Public Law 111–148, Sec. 4205(d), 124 Stat. 119, 576 (2010).)

We interpret the provisions of section 4205 of the ACA related to preemption to mean that States and local governments may not impose nutrition labeling requirements for food sold from vending machines that must comply with the Federal requirements of section 403(q)(5)(H) of the FD&C Act, unless the State or local requirements are identical to the Federal requirements. In other words, States and localities cannot have additional or different nutrition labeling requirements for food sold either: (1) From vending machines that are operated by a person engaged in the business of owning or operating 20 or more vending machines subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act or (2) from vending machines operated by a person not subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act who voluntarily elects to be subject to those requirements by registering biannually under section 403(q)(5)(H)(ix) of the FD&C Act.

Otherwise, for food sold from vending machines not subject to the nutrition labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act, States and localities may impose nutrition labeling requirements. Under our interpretation of the Rule of Construction in section 4205(d)(1) of the ACA, nutrition labeling for food sold from these vending machines would not be ''nutrient content disclosures of the type required under section 403(q)(5)(H)(viii) [of the FD&C Act]'' and, therefore, would not be preempted. Under this interpretation, States and localities would be able to continue to require nutrition labeling for food sold from vending machines which are exempt from nutrition labeling under section 403(q)(5) of the FD&C Act. This interpretation is consistent with the fact that Congress included vending machine operators in the voluntary registration provision of section 403(q)(5)(H)(ix) of the FD&C Act. There would have been no need to include vending machine operators in the provision that allows opting into the Federal requirements if States and localities could not otherwise require non-identical nutrition labeling for food sold from any vending machines.

The preamble to the proposed rule (76 FR 19238 at 19252) described an alternative interpretation of section 4205 of the ACA that could leave less room for States and localities to require nutrition labeling for food sold from vending machines. Under this alternative interpretation, State or local nutrition labeling requirements for food sold from vending machines would be preempted because such nutrition labeling requirements would be ''nutrition content disclosures of the type required under section 403(q)(5)(H) [of the FD&C Act]'' and would not fall within the exception to preemption in section 403A(a)(4) of the FD&C Act (''except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations . . .'').

Under this alternative interpretation, States and localities could not have nutrition labeling requirements for food sold in vending machines that were not identical to the Federal requirements, unless they successfully petitioned FDA. The position that no State or locality may have a vending machine food nutrition labeling requirement not identical to the Federal requirements, regardless of how many vending machines the operator owns or operates, was the position in the guidance we issued (entitled ''Guidance for Industry: Questions and Answers Regarding the Effect of Section 4205 of the Patient Protection and Affordable Care Act of 2010 on State and Local Menu and Vending Machine Labeling Laws'' (75 FR 52427, August 25, 2010)). Federal law provides that, upon petition, we may exempt State or local requirements from the express preemption provisions of section 403A(a) of the FD&C Act under certain conditions (21 U.S.C. 343–1(b)). We have issued regulations at § 100.1 (21 CFR 100.1) describing the petition process that is available to State and local governments to request such exemptions from preemption. Under our proposed interpretation, for food sold from vending machines that is not subject to the nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act, States and localities may establish or continue to impose nutrition labeling requirements. Under the alternative interpretation, there would be food sold in vending machines for which the Federal Government has not required nutrition labeling and for which States and localities would be precluded from establishing such labeling requirements unless they successfully petitioned FDA and a rulemaking was completed. This approach would risk creating a regulatory gap that would be inconsistent with the purposes of section 4205 of the ACA. It would also impose a restriction and burden on the States and localities that is inconsistent with the Federalism principles expressed in Executive Order 13132, as well as a substantial administrative burden on FDA if States petition for exemption.

We invited comments on our interpretation of section 4205 of the ACA related to preemption, as well as on the alternative interpretation described in the Federalism section. We also requested comments on the use of the petition process in this context and on other potential interpretations that interested persons identify as appropriate given both the preemption-related language of section 4205 of the ACA and the statutory goals.

(Comment 41) Several comments supported the preemptive scope being limited to State and local requirements imposing additional or different nutritional labeling requirements for food sold from covered vending machines, including food sold from machines operated by a person who has elected to be subject to the requirements of section 403(q)(5)(H) of the FD&C Act (76 FR 19238 at 19251–19252). Some comments stated that the alternative interpretation, that no State or locality may have a vending machine food nutrition labeling requirement that is not identical to the Federal requirements regardless of how many vending machines the operator owns or operates, would restrict State and local

authorities and create a ''regulatory vacuum'' because the Federal system exempts vending machine operators with fewer than 20 machines. A few comments stated that the alternative interpretation, which would create a gap in coverage of vending machines, would be inconsistent with the purposes and language of section 4205 of the ACA. These comments also stated that imposing a restriction on States and localities is inconsistent with Federalism principles expressed in Executive Order 13132. Another comment stated that section 4205 of the ACA intends that States and localities have authority to regulate nutritional information for machines that do not come under the purview of the Federal law.

Several comments would have us revise the rule to clarify that ''identical'' does not mean verbatim in wording rather in effect. One comment suggested the following language: ''The specific words of the State or local requirements need not be the same. State or local requirements that are worded differently from the Federal requirements and/or provide for different enforcement schemes may still be 'identical' under [section 4205 of the ACA].''

Other comments noted that the savings clause for warnings about the safety of food is included in the Rule of Construction in section 4205(d) of the ACA. A few comments suggested that we codify the Rule of Construction because its omission from the rule may lead to confusion over how the statute should be interpreted. The comments noted that the lack of a codified statement for a similar rule of construction in the NLEA has led to confusion and to court decisions that did not take that rule of construction into account. One comment stated that we should include a savings clause that expressly identifies that nutrition labeling for less than 20 machines is not preempted in the absence of voluntary compliance by non-covered vending machine operators.

(Response 41) We agree with the comments asserting that the preemptive effect of the Federal nutrition labeling requirements of section 4205 of the ACA for food sold from vending machines is limited to State and local requirements that impose additional or different nutrition labeling requirements for food sold from vending machines that are covered by the Federal requirements of section 403(q)(5)(H) of the FD&C Act and § 101.8. We also agree that the alternative interpretation described in the proposed rule (76 FR 19238 at 19251 through 19252), that no State or locality may have a nutrition labeling requirement for food sold from vending machines that is not identical to the Federal requirements regardless of how many vending machines the operator owns or operates, would restrict State and local authorities and create a regulatory gap that would be inconsistent with the purposes and language of section 4205 of the ACA and the Federalism principles expressed in Executive Order 13132. In addition, as we noted in the preamble to the proposed rule (76 FR 19238 at 19251 through 19252), there would be no reason for Congress to include vending machine operators in the voluntary registration provision of section 403(q)(5)(H)(ix) of the FD&C Act, which allows vending machine operators not subject to the requirements of section 403(q)(5)(H) of the FD&C Act to opt into the Federal requirements if State and local governments could not otherwise require non-identical nutrition labeling for food sold from any vending machines.

For these reasons, we interpret the provisions of section 4205 of the ACA related to preemption to mean that States and local governments may not establish or continue into effect nutrition labeling requirements for food sold from vending machines covered by the Federal requirements of section 403(q)(5)(H) of the FD&C Act and § 101.8, unless the State or local requirements are identical to the Federal requirements of section 403(q)(5)(H) of the FD&C Act and § 101.8. In other words, States and localities cannot have additional or different nutrition labeling requirements for food sold either from: (1) Vending machines that are operated by a person engaged in the business of owning or operating 20 or more vending machines subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8; or (2) vending machines operated by a person not otherwise subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8 who voluntarily elects to be subject to those requirements by registering biannually with FDA in accordance with section 403(q)(5)(H)(ix) of the FD&C Act and § 101.8(d). For food sold from vending machines not subject to the nutrition labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act, States and localities may impose nutrition labeling requirements.

In response to the comments asserting that we revise the rule to clarify the meaning of ''identical'' within the context of section 403A(a)(4) of the FD&C Act, we note that we have already issued a regulation at § 100.1 that explains the meaning of ''not identical to'' in the context of section 403A of the FD&C Act in describing the petition process available to State and local governments to request an exemption from the express preemption provisions of section 403A of the FD&C Act under section 403A(b) of the FD&C Act. FDA regulations, at § 100.1(c)(4), provide, in relevant part, that, within the context of section 403A of FD&C Act, ''not identical to'' does not refer to the specific words in the State or local requirement but instead means that the State or local requirement directly or indirectly imposes obligations or contains provisions concerning the labeling of food that: (1) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 403 of the FD&C Act or (2) differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 403 of the FD&C Act. Accordingly, a State or local nutrition labeling requirement for food sold from vending machines covered by the requirements of section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8 that directly or indirectly imposes obligations or contains labeling provisions that: (1) Are not imposed by or contained in section 403(q) of the FD&C Act and § 101.8; or (2) differ from those specifically imposed by or contained in section 403(q) of the FD&C Act and § 101.8 would be ''not identical to'' the Federal requirements and therefore would be preempted under section 403A(a)(4) of the FD&C Act. Because the meaning of the phrase ''not identical to,'' within the context of section 403A of the FD&C Act, is already described in § 100.1 and is further clarified here in the context of vending machines, we decline to revise the rule to clarify the meaning of ''identical'' as suggested by the comments.

We decline to amend § 101.8 to restate the Rule of Construction at section 4205(d) of the ACA or to add a savings clause that expressly provides that nutrition labeling for fewer than 20 vending machines is not preempted in the absence of voluntary compliance. As discussed in section III.C.4.a of this preamble, and specified in § 101.8(c)(1), § 101.8 only applies to food sold from a vending machine that: (1) Is operated by a person engaged in the business of owning or operating 20 or more machines; or (2) is operated by a vending machine operator that has voluntarily elected to be subject to § 101.8 by registering with FDA in accordance with § 101.8(d). In addition, we explain our interpretation of the provisions of section 4205 of the ACA

related to preemption mentioned previously, including our interpretation that State and local governments may impose nutrition labeling requirements for food sold from vending machines not subject to the requirements of section 403(q)(5)(H) of the FD&C Act, which would include vending machines operated by a person engaged in the business of owning or operating fewer than 20 vending machines. Because § 101.8(c)(1) specifies what foods and vending machines are covered by the requirements of section 403(q)(5)(H) and § 101.8, and we have described the Rule of Construction at section 4205(d) of the ACA and explained our interpretation of the provisions of section 4205 of the ACA related to preemption mentioned previously, we decline to revise § 101.8 as suggested by the comments.

VII. Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

1. FDA/CFSAN, ''Food Labeling: Calorie Labeling of Articles of Food in Vending Machines, Regulatory Impact Analysis,'' 2014.
2. FDA/CFSAN, ''Food Labeling: Calorie Labeling of Articles of Food in Vending Machines NPRM, Preliminary Regulatory Impact Analysis,'' 2011.
3. Memo to File. Correspondence with Eric Dell of the National Automatic Merchandising Association. April 10, 2013.
4. Memo to File. Correspondence with Eric Dell of the National Automatic Merchandising Association. April 13, 2013.
5. Eastern Research Group I. ''Evaluation of Recordkeeping Costs for Food Manufacturers, Final Report,'' A. Sertkaya, A. Berlind, and S. Erdem, Eds. Contract No. 223–01–2461, Task Order Number 5. 2007.
6. ''2012 Census of the Industry,'' *Vending Times,* 2012; 52(12).
7. 2012 State of the Vending Industry Report, 2013,'' *Automatic Merchandiser.*
8. National Automatic Merchandising Association. Comments of: The National Automatic Merchandising Association. Docket No. FDA–2010–N–0298. 2010.

List of Subjects

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 11 and 101 are amended as follows:

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 1. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 2. Section 11.1 is amended by adding paragraph (h) to read as follows:

§ 11.1 Scope.

* * * * *

(h) This part does not apply to electronic signatures obtained under § 101.8(d) of this chapter.

PART 101—FOOD LABELING

■ 3. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 4. Section 101.8 is added to subpart A to read as follows:

§ 101.8 Vending machines.

(a) *Definitions.* The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this section. In addition, for the purposes of this section:

Authorized official of a vending machine operator means an owner, operator, agent in charge, or any other person authorized by a vending machine operator who is not otherwise subject to section 403(q)(5)(H)(viii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)(viii)), to register the vending machine operator with the Food and Drug Administration (''FDA'') for purposes of paragraph (d) of this section.

Vending machine means a self-service machine that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses servings of food in bulk or in packages, or prepared by the machine, without the necessity of replenishing the machine between each vending operation.

Vending machine operator means a person(s) or entity that controls or directs the function of the vending machine, including deciding which articles of food are sold from the machine or the placement of the articles of food within the vending machine, and is compensated for the control or direction of the function of the vending machine.

(b) *Articles of food not covered.* Articles of food sold from a vending machine are not covered vending machine food if:

(1) The prospective purchaser can view:

(i) The calories, serving size, and servings per container listed in the Nutrition Facts label on the vending machine food without any obstruction. The Nutrition Facts label must be in the format required in § 101.9(c) and (d). The Nutrition Facts label must be in a size that permits the prospective purchaser to be able to easily read the nutrition information contained in the Nutrition Facts label on the article of food in the vending machine. Smaller formats allowed for Nutrition Facts for certain food labeling under FDA regulation at § 101.9 are not considered to be a size that a prospective purchaser is able to easily read; or

(ii) The calories, serving size, and servings per container listed in a reproduction of the Nutrition Facts label on the vending machine food, provided that the reproduction is a reproduction of an actual Nutrition Facts label that complies with § 101.9 for a vending machine food, is presented in a size that permits the prospective purchaser to be able to easily read the nutrition information, and the calories, serving size, and servings per container are displayed by the vending machine before the prospective purchaser makes his or her purchase; or

(2) The prospective purchaser can otherwise view visible nutrition information, including, at a minimum the total number of calories for the article of food as sold at the point of purchase. This visible nutrition information must appear on the food label itself. The visible nutrition information must be clear and conspicuous and able to be easily read on the article of food while in the vending machine, in a type size at least 50 percent of the size of the largest printed matter on the label and with sufficient color and contrasting background to other print on the label

to permit the perspective purchaser to clearly distinguish the information.

(c) *Requirements for calorie labeling for certain food sold from vending machines*—(1) *Applicability; covered vending machine food.* For the purposes of this section, the term ''covered vending machine food'' means an article of food that is:

(i) Sold from a vending machine that does not permit the prospective purchaser to examine the Nutrition Facts label prior to purchase as provided in paragraph (b)(1) of this section or otherwise provide visible nutrition information at the point of purchase as provided in paragraph (b)(2) of this section; and

(ii) Sold from a vending machine that:

(A) Is operated by a person engaged in the business of owning or operating 20 or more vending machines; or

(B) Is operated by a vending machine operator that has voluntarily elected to be subject to the requirements of this section by registering with FDA under paragraph (d) of this section.

(2) *Calorie declaration.* (i) The number of calories for a covered vending machine food must be declared in the following manner:

(A) To the nearest 5-calorie increment up to and including 50 calories and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero.

(B) The term ''Calories'' or ''Cal'' must appear adjacent to the caloric content value for each food in the vending machine.

(C) The calorie declaration for a packaged food must include the total calories present in the packaged food, regardless of whether the packaged food contains a single serving or multiple servings. The vending machine operator may voluntarily disclose calories per serving in addition to the total calories for the food.

(D) If a covered vending machine food is one where the prospective purchaser selects among options to produce a final vended product (*e.g.,* vended coffee, hot chocolate or tea with options for added sugar, sugar substitute, milk, and cream), calories must be declared per option or for the final vended products.

(ii) Calorie declarations for covered vending machine food must be clear and conspicuous and placed prominently in the following manner:

(A) The calorie declarations may be placed on a sign in close proximity to the article of food or selection button, *i.e.,* in, on, or adjacent to the vending machine, but not necessarily attached to the vending machine, so long as the calorie declaration is visible at the same time as the food, its name, price, selection button, or selection number is visible. The sign must give calorie declarations for those articles of food that are sold from that particular vending machine.

(B) When the calorie declaration is in or on the vending machine, the calorie declaration must be in a type size no smaller than the name of the food on the machine (not the label), selection number, or price of the food as displayed on the vending machine, whichever is smallest, with the same prominence, *i.e.,* the same color, or in a color at least as conspicuous, as the color of the name, if applicable, or price of the food or selection number, and the same contrasting background, or a background at least as contrasting as the background used for the item it is in closest proximity to, *i.e.,* name, selection number, or price of the food item as displayed on the machine.

(C) When the calorie declaration is on a sign adjacent to the vending machine, the calorie declaration must be in a type size large enough to render it likely to be read and understood by the prospective purchaser under customary conditions of purchase and use, and in a type that is all black or one color on a white or other neutral background that contrasts with the type color.

(D) Where the vending machine only displays a picture or other representation or name of the food item, the calorie declaration must be in close proximity to the picture or other representation or name, or in close proximity to the selection button.

(E) For electronic vending machines (*e.g.,* machines with digital or electronic or liquid crystal display (LCD) displays), the calorie declaration must be displayed before the prospective purchaser makes his or her purchase.

(F) For vending machines with few choices, *e.g.,* popcorn, the calorie declaration may appear on the face of the machine so long as the declaration is prominent, not crowded by other labeling on the machine, and the type size is no smaller than the name of the food on the machine (not the label), selection number, or price of the food as displayed on the vending machine, whichever is smallest.

(d) *Voluntary provision of calorie labeling for foods sold from vending machines*—(1) *Applicability.* A vending machine operator that is not subject to the requirements of section 403(q)(5)(H)(viii) of the Federal Food, Drug, and Cosmetic Act may, through its authorized official, voluntarily register with FDA to be subject to the requirements established in paragraph (c)(2) of this section. An authorized official of a vending machine operator that voluntarily registers cannot be subject to any State or local nutrition labeling requirements that are not identical to the requirements in 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act.

(2) *Who may register*? A vending machine operator that is not otherwise subject to the requirements of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act may register with FDA.

(3) *What information is required*? The vending machine operator must provide FDA with the following information:

(i) The contact information (including name, address, phone number, email address), for the vending machine operator;

(ii) The address of the location of each vending machine owned or operated by the vending machine operator that is being registered;

(iii) Preferred mailing address (if different from the vending machine operator address), for purposes of receiving correspondence; and

(iv) Certification that the information submitted is true and accurate, that the person or firm submitting it is authorized to do so, and that each registered vending machine will be subject to the requirements of this section.

(v) Information should be submitted by email by typing complete information into the portable document format (PDF) form, saving it on the registrant's computer, and sending it by email to *menulawregistration@fda.hhs.gov.* If email is not available, the registrant can either fill in the PDF form and print it out (or print out the blank PDF and fill in the information by hand or typewriter), and either fax the completed form to 301–436–2804 or mail it to FDA, CFSAN Menu and Vending Machine Labeling Registration, White Oak Building 22, rm. 0209, 10903 New Hampshire Ave., Silver Spring, MD 20993.

(vi) Authorized officials of a vending machine operator who elect to be subject to the Federal requirements can register by visiting *http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm217762.htm.* FDA has created a form that contains fields requesting the information in paragraph (d) of this section and made the form available at this Web site. Registrants must use this form to ensure that complete information is submitted.

(vii) To keep the establishment's registration active, the authorized official of the vending machine operator must register every other year within 60 days prior to the expiration of the vending machine operator's current

registration with FDA. Registration will automatically expire if not renewed.

(e) *Vending machine operator contact information.* (1) A vending machine operator that is subject to section 403(q)(5)(H)(viii) of the Federal Food, Drug, and Cosmetic Act or a vending machine operator that voluntarily registers to be subject to the requirements under paragraph (d) of this section must provide its contact information for vending machines selling covered vending machine food. The contact information must list the vending machine operator's name, telephone number, and mailing address or email address.

(2) The contact information must be readable and may be placed on the face of the vending machine, or otherwise must be placed with the calorie declarations as described in paragraph (c)(2)(ii) of this section (*i.e.,* on the sign in, on, or adjacent to the vending machine).

(f) *Signatures.* Signatures obtained under paragraph (d) of this section that meet the definition of electronic signatures in § 11.3(b)(7) of this chapter are exempt from the requirements of part 11 of this chapter.

■ 5. In § 101.9, revise paragraphs (j)(2)(ii) and (j)(4) and the introductory text of paragraph (j)(13)(i) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(j) * * *

(2) * * *

(ii) Served in other establishments in which food is served for immediate human consumption (*e.g.,* institutional food service establishments, such as schools, hospitals, and cafeterias; transportation carriers, such as trains and airplanes; bakeries, delicatessens, and retail confectionery stores where there are facilities for immediate consumption on the premises; food service vendors, such as lunch wagons, ice cream shops, mall cookie counters, vending machines, and sidewalk carts where foods are generally consumed immediately where purchased or while the consumer is walking away, including similar foods sold from convenience stores; and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices), *Provided,* That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising, except as provided in § 101.8(c). Claims or other nutrition information, except as provided in § 101.8(c), subject the food to the provisions of this section;

* * * * *

(4) Foods that contain insignificant amounts of all of the nutrients and food components required to be included in the declaration of nutrition information under paragraph (c) of this section, *Provided,* That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising, except as provided in § 101.8(c). Claims or other nutrition information, except as provided in § 101.8(c), subject the food to the provisions of this section. An insignificant amount of a nutrient or food component shall be that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrate, dietary fiber, and protein, it shall be an amount that allows a declaration of ''less than 1 gram.'' Examples of foods that are exempt under this paragraph include coffee beans (whole or ground), tea leaves, plain unsweetened instant coffee and tea, condiment-type dehydrated vegetables, flavor extracts, and food colors.

* * * * *

(13)(i) Foods in small packages that have a total surface area available to bear labeling of less than 12 square inches, *Provided,* That the labels for these foods bear no nutrition claims or other nutrition information in any context on the label or in labeling or advertising, except as provided in § 101.8(c). Claims or other nutrition information, except as provided in § 101.8(c), subject the food to the provisions of this section.

* * * * *

Dated: November 19, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27834 Filed 11–25–14; 8:45 am]

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LIST OF PUBLIC LAWS

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When a date falls on a weekend or holiday, the next Federal business day is used. (See 1 CFR 18.17)

A new table will be published in the first issue of each month.

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