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RESERVATIONS: (202) 741–6008

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Contents

Federal Register

Vol. 76, No. 120

Wednesday, June 22, 2011

Agency for Healthcare Research and Quality
NOTICES
Scientific Information Requests:
Insulin Delivery and Glucose Monitoring Devices for Diabetes Mellitus, 36539–36541

Agency for International Development
NOTICES
Meetings:
Board for International Food and Agricultural Development; Amendment, 36512

Agricultural Marketing Service
RULES
Mango Promotion, Research, and Information Order; Reapportionment, 36281–36283

Agricultural Research Service
NOTICES
Intents to Grant Exclusive Licenses, 36513

Agriculture Department
See Agricultural Marketing Service
See Agricultural Research Service
See Economic Research Service
See Forest Service
See National Agricultural Statistics Service
NOTICES
Increases in Domestic Sugar Overall Allotment Quantity, etc., 36512–36513

Coast Guard
RULES
Safety Zones:
Mile Marker 98.5 West to Mile Marker 108.5 West of Harvey Lock Gulf Intracoastal Waterway, 36314–36316
Upper Mississippi River, Mile 180.0 to 179.0, 36316–36318
Waterway Closure, Morgan City – Port Allen Route from Mile Marker 0 to Port Allen Lock, 36318–36320
Special Local Regulations for Marine Events:
Temporary Change of Dates for Recurring Marine Events in the Fifth Coast Guard District, Mill Creek, Hampton, VA, 36308–36311
Special Local Regulations:
Extreme Sailing Series Boston, Boston Harbor, Boston, MA, 36311–36314
PROPOSED RULES
Safety Zones:
Patuxent River, MD, 36447–36450
Special Local Regulations; Safety and Security Zones:
Recurring Events in Captain of the Port Long Island Sound Zone, 36438–36447

Commerce Department
See International Trade Administration
See National Oceanic and Atmospheric Administration

Commodity Futures Trading Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Exemptions from Speculative Limits, 36525–36526

Drug Enforcement Administration
NOTICES
Manufacturers of Controlled Substances; Applications, 36577–36578
Manufacturers of Controlled Substances; Registrations, 36578

Economic Research Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 36513–36515

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 36526

Employee Benefits Security Administration
NOTICES
Meetings:
Advisory Council on Employee Welfare and Pension Benefit Plans, 36578

Energy Department
See Federal Energy Regulatory Commission

Environmental Protection Agency
RULES
Approvals and Promulgations of Air Quality Implementation Plans:
Virginia; Adoption of Revised Nitrogen Dioxide Standard, 36326–36329
Approvals and Promulgations of Implementation Plans:
Idaho; Regional Haze State Implementation Plan and Interstate Transport Plan, 36329–36339
Exemptions from the Requirements of Tolerances:
2–methyl–2,4–pentanediol, 36342–36349
C9 Rich Aromatic Hydrocarbons, C10–11 Rich Aromatic Hydrocarbons, and C11–12 Rich Aromatic Hydrocarbons, 36356–36362
Diethylene Glycol MonoEthyl Ether, 36349–36356
Hazardous Waste Manifest Printing Specifications, 36363–36366
Mandatory Reporting of Greenhouse Gases; Additional Sources of Fluorinated GHGs:
Extension of Best Available Monitoring Provisions for Electronics Manufacturing, 36339–36342
PROPOSED RULES
Approvals and Promulgations of Air Quality Implementation Plans:
Nevada; Regional Haze State Implementation Plan, 36450–36468
North Carolina; Clean Smokestacks Act, 36468–36471
Virginia; Adoption of Revised Nitrogen Dioxide Standard, 36471–36472
Hazardous Waste Manifest Printing Specifications, 36480–36482

Mandatory Reporting of Greenhouse Gases:
Changes to Provisions for Electronics Manufacturing to Provide Flexibility, 36472–36479
Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities, 36479–36480
NOTICES
Public Comment Periods on Draft Addendums and Peer Review Workshops:
Toxicological Review of Methanol (Non-Cancer) in Support of Summary Information on Integrated Risk Information System, 36534–36535
Requests to Voluntarily Cancel Certain Pesticide Registrations:
Dicofol, 36535–36537

Executive Office of the President
See Presidential Documents

Federal Aviation Administration
RULES
Airworthiness Directives:
Dassault Aviation Model FALCON 7X Airplanes, 36283–36285
Establishments of Class E Airspace:
Brunswick, ME, 36285–36286
Modifications of Class E Airspace:
Newcastle, WY, 36286–36287
PROPOSED RULES
Airworthiness Directives:
Airbus Models A300–600 Series Airplanes, 36387–36390
BAE SYSTEMS (OPERATIONS) LIMITED Model BAe 146 and Avro 146 RJ Airplanes, 36398–36400
Boeing Co. Model 747SP Series Airplanes, 36390–36392
Gulfstream Aerospace Corp. Model GV and GV SP Airplanes, 36392–36395
Piper Aircraft, Inc. Models PA–24, PA–24–250, and PA 24–260 Airplanes, 36395–36398

Federal Communications Commission
RULES
Radio Broadcasting Services:
Brackettville, TX, 36384–36385

Federal Contract Compliance Programs Office
PROPOSED RULES
Affirmative Action and Nondiscrimination Obligations of Contractors and Subcontractors Regarding Protected Veterans, 36482

Federal Emergency Management Agency
RULES
Final Flood Elevation Determinations, 36373–36384
Suspensions of Community Eligibility, 36369–36373
PROPOSED RULES
Flood Elevation Determinations, 36482–36486
NOTICES
Major Disaster Declarations:
Illinois; Amendment No. 1, 36558
South Dakota; Amendment No. 2, 36558–36559
South Dakota; Amendment No. 3, 36559
Major Disasters and Related Determinations:
Oklahoma, 36559

Federal Energy Regulatory Commission
PROPOSED RULES
Third-Party Provision of Ancillary Services:
Accounting and Financial Reporting for New Electric Storage Technologies, 36400–36410
NOTICES
Applications:
Alabama Power Co., 36527–36528
Columbia Gas Transmission, LLC, 36526–36527
Combined Filings, 36528–36532
Complaints:
Iberdrola Renewables, Inc.; PacifiCorp; NextEra Energy Resources, LLC et al. v. Bonneville Power Administration, 36532
Complaints; Amendments:
Gregory R. Swecker, Beverly F. Swecker v. Midland Power Cooperative State of Iowa, 36532–36533
Requests for Blanket Authorizations:
Transcontinental Gas Pipe Line Co., LLC, 36533
Waivers; Requests:
Bangor Hydro Electric Co., 36533–36534

Federal Highway Administration
PROPOSED RULES
Value Engineering, 36410–36414
NOTICES
Environmental Impact Statements; Availability, etc.:
Nueces County, TX, 36613–36614
Limitations on Claims for Judicial Reviews of Actions:
Final Federal Agency Action on Proposed Highway in Illinois, 36614–36615

Federal Maritime Commission
NOTICES
Agreements Filed, 36537–36538

Federal Reserve System
NOTICES
Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 36538
Proposals to Engage in Permissible Nonbanking Activities or Acquire Companies Engaged in Permissible Nonbanking Activities, 36538

Fish and Wildlife Service
PROPOSED RULES
Endangered and Threatened Wildlife and Plants:
Eskimo Curlew; Initiation of 5-Year Status Review, 36491–36493
Establishment of Manatee Refuge in Kings Bay, Citrus County, FL, 36493–36508
Supplemental Proposals for Migratory Game Bird Hunting Regulations for the 2011–12 Hunting Season, 36508–36510
NOTICES
Environmental Assessments; Availability, etc.:
Bowdoin National Wildlife Refuge Complex, Malta, MT; Comprehensive Conservation Plan, 36571–36573

Food and Drug Administration
RULES
Required Warnings for Cigarette Packages and Advertisements, 36628–36777
Small Entity Compliance Guide; Availability:
Topical Acne Drug Products for Over-the-Counter Human Use—Revision of Labeling, etc., 36307–36308
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Prescription Drug Advertisements, 36541–36542
Draft Guidance for Industry and Staff; Availability:
Content of Investigational Device Exemption and Premarket Approval Applications for Low Glucose Suspend Device Systems, 36542–36543

Draft Guidance for Industry; Availability:
Applying Human Factors and Usability Engineering to Optimize Medical Device Design, 36543–36544
Meetings:
Circulatory System Devices Panel of Medical Devices Advisory Committee, 36548
Scientific Evaluation of Modified Risk Tobacco Product Applications; Public Workshop, 36544–36548
Regulatory Review Period for Purposes of Patent Extension:
METVIXIA, 36548–36549

Forest Service
NOTICES
Environmental Impact Statements; Availability, etc.:
Rangeland Allotment Management Planning on Fall River and Oglala Geographic Areas, NE and SD, 36515–36517
Meetings:
Colorado Recreation Resource Advisory Committee; Federal Lands Recreation Enhancement Act, 36518
Plumas County Resource Advisory Committee, 36517

Health and Human Services Department
See Agency for Healthcare Research and Quality
See Food and Drug Administration
See National Institutes of Health
See Substance Abuse and Mental Health Services Administration
RULES
National Vaccine Injury Compensation Program; Revisions to the Vaccine Injury Table, 36367–36369
NOTICES
Meetings:
Technical Advisory Panel on Medicare Trustee Reports, 36539
Statements of Organization, Functions, and Delegations of Authority, 36539

Homeland Security Department
See Coast Guard
See Federal Emergency Management Agency
See Transportation Security Administration
See U.S. Citizenship and Immigration Services
See U.S. Immigration and Customs Enforcement

Housing and Urban Development Department
RULES
Adjustment of Civil Money Penalty Amount for Inflation, 36850–36851
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
HOPE VI Application, 36564–36565
Logic Model Grant Performance Report Standard, 36566–36567
Public Housing Financial Management Template, 36565
Public Housing Inventory Removal Application, 36565–36566
Delegations of Authority:
Office of Departmental Equal Employment Opportunity, 36567
Funding Awards:
Indian Community Development Block Grant Program Fiscal Year 2010, 36567–36571

Interior Department
See Fish and Wildlife Service
See Land Management Bureau
See Surface Mining Reclamation and Enforcement Office

Internal Revenue Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 36618–36623
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Regulation Project, 36623–36625

International Trade Administration
NOTICES
Antidumping Duty Administrative Reviews; Extensions of Final Results:
Certain Frozen Warmwater Shrimp from Socialist Republic of Vietnam, 36519
Antidumping Duty Administrative Reviews; Preliminary Results:
Purified Carboxymethylcellulose from Netherlands, 36519–36525

International Trade Commission
NOTICES
Investigations:
Certain Flip-Top Vials and Products Using Same, 36576–36577

Justice Department
See Drug Enforcement Administration
NOTICES
Lodging of Consent Decrees, 36577

Labor Department
See Employee Benefits Security Administration
See Federal Contract Compliance Programs Office
See Occupational Safety and Health Administration

Land Management Bureau
NOTICES
Public Land Orders:
No. 7770; Extension of No. 6884; Alaska, 36573
Public Land Orders; Extensions:
No. 6888, Alaska, 36574

Legal Services Corporation
NOTICES
Meetings; Sunshine Act, 36580

National Agricultural Statistics Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 36518–36519

National Highway Traffic Safety Administration
PROPOSED RULES
Preliminary Theft Data; Motor Vehicle Theft Prevention Standard, 36486–36491
NOTICES
Petitions for Exemptions from Vehicle Theft Prevention Standard:
Nissan, 36615–36617

National Institutes of Health
NOTICES
Government-Owned Inventions; Availability for Licensing, 36549–36554
Meetings:
Center for Scientific Review, 36555–36556

National Center for Research Resources, 36556
National Institute of Diabetes and Digestive and Kidney Diseases, 36554–36555
National Institute of General Medical Sciences, 36556
Prospective Grants of Exclusive Licenses:
Development of Ulipristal Acetate for Treatment of Symptomatic Uterine Fibroids, 36556–36557
Devices for Clearing Mucus from Endotracheal Tubes, 36557

National Labor Relations Board
PROPOSED RULES
Representation Case Procedures, 36812–36847

National Oceanic and Atmospheric Administration
PROPOSED RULES
Fisheries of the Northeastern United States:
Atlantic Deep-Sea Red Crab; Amendment 3, 36511

Nuclear Regulatory Commission
RULES
Revisions of Fee Schedules:
Fee Recovery for Fiscal Year 2011, 36780–36809
PROPOSED RULES
Petition for Rulemaking Submitted by Annette User on Behalf of GE Osmonics, Inc., 36386–36387

Occupational Safety and Health Administration
PROPOSED RULES
Occupational Injury and Illness Recording and Reporting Requirements:
NAICS Update and Reporting Revisions, 36414–36438
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Onsite Consultation Agreements, 36579–36580

Personnel Management Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Disabled Dependent Questionnaire, 36582
Health Benefits Election Form, 36582–36583
Life Insurance Election, 36583
USAJOBS, 36581

Postal Regulatory Commission
NOTICES
New Postal Products, 36583–36584

Postal Service
RULES
Rules of Practice in Proceedings Relative to False Representation and Lottery Orders, 36320–36326

Presidential Documents
PROCLAMATIONS
Special Observances:
Father's Day (Proc. 8690), 36853–36856

Securities and Exchange Commission
RULES
Exemptive Orders:
Temporary Exemptions and Other Temporary Relief Applicable to Security-Based Swaps, 36287–36307
NOTICES
Applications:
Highmark Funds and Highmark Capital Management, Inc., 36584–36585
Self-Regulatory Organizations; Proposed Rule Changes:
Chicago Stock Exchange, Inc., 36596–36598
Financial Industry Regulatory Authority, Inc., 36586–36596
NASDAQ OMX PHLX LLC, 36606–36607
NASDAQ Stock Market LLC, 36610–36612
NYSE Amex LLC, 36598–36600
NYSE Arca, Inc., 36600–36606, 36608–36610

State Department
NOTICES
Determinations Pursuant to Foreign Missions Act, 36612
Meetings:
Shipping Coordinating Committee, 36613
U.S. Advisory Commission on Public Diplomacy, 36612–36613

Statistical Reporting Service
See National Agricultural Statistics Service

Substance Abuse and Mental Health Services Administration
NOTICES
Meetings
Drug Testing Advisory Board, 36557–36558

Surface Mining Reclamation and Enforcement Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 36574–36576

Surface Transportation Board
NOTICES
Abandonment Exemptions:
Union Pacific Railroad Co., Freeborn County, MN, 36617

Thrift Supervision Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Amendment of Federal Savings Association Charter, 36626
Application and Termination Notice for Municipal Securities Dealer Principal or Representative, 36625
Mutual Holding Company, 36625–36626

Transportation Department
See Federal Aviation Administration
See Federal Highway Administration
See National Highway Traffic Safety Administration
See Surface Transportation Board
See Transportation Security Administration

Transportation Security Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Security Threat Assessment for Individuals Applying for Hazardous Materials Endorsement for Commercial Drivers License, 36560

Treasury Department
See Internal Revenue Service
See Thrift Supervision Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 36617–36618

U.S. Citizenship and Immigration Services
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application to File Declaration of Intention, 36560–36561

U.S. Immigration and Customs Enforcement
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Fee Remittance for Certain F, J and M Non-Immigrants, 36562
Nonimmigrant Checkout Letter, 36562–36563
Obligor Change of Address, 36561–36562
Suspicious/Criminal Activity Tip Reporting, 36563–36564

Separate Parts In This Issue

Part II
Health and Human Services Department, Food and Drug Administration, 36628–36777

Part III
Nuclear Regulatory Commission, 36780–36809

Part IV
National Labor Relations Board, 36812–36847

Part V
Housing and Urban Development Department, 36850–36851

Part VI
Presidential Documents, 36853–36856

Reader Aids

Consult the Reader Aids section at the end of this page for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

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

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR
Proclamations:
8690 36855

7 CFR
1206 36281

10 CFR
170 36780
171 36780
Proposed Rules:
30 36386

14 CFR
39 36283
71 (2 documents) 36285, 36286
Proposed Rules:
39 (5 documents) 36387, 36390, 36392, 36395, 36398

17 CFR
240 36287

18 CFR
Proposed Rules:
Ch. I 36400

21 CFR
333 36307
1141 36628

23 CFR
Proposed Rules:
627 36410

24 CFR
30 36850

29 CFR
Proposed Rules:
101 36812
102 36812
103 36812
1904 36414

33 CFR
100 (2 documents) 36308, 36311
165 (3 documents) 36314, 36316, 36318
Proposed Rules:
100 36438
165 (2 documents) 36438, 36447

39 CFR
952 36320

40 CFR
52 (2 documents) 36326, 36329
98 36339
180 (3 documents) 36342, 36349, 36356
262 36363
Proposed Rules:
51 36450
52 (2 documents) 36468, 36471
98 36472
174 36479
180 36479
262 36480

41 CFR
Proposed Rules:
60-250 36482
60-300 36482

42 CFR
100 36367

44 CFR
64 36369
67 36373
Proposed Rules:
67 36482

47 CFR
73 36384

49 CFR
Proposed Rules:
541 36486

50 CFR
Proposed Rules:
17 (2 documents) 36491, 36493
20 36508
648 36511

Rules and Regulations

Federal Register
Vol. 76, No. 120
Wednesday, June 22, 2011

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1206

[Doc. No. AMS–FV–10–0092]

Mango Promotion, Research, and Information Order; Reapportionment

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule reduces the number of National Mango Board (Board) members from 20 to 18 to reflect the elimination of two non-voting wholesaler/retailer positions. In accordance with the Mango Promotion, Research, and Information Order (Order), which is authorized under the Commodity Promotion, Research, and Information Act of 1996 (Act), a review of the composition of the Board must be conducted every five years. The Board reviewed the production volumes and geographical distribution of domestic and imported mangos, and submitted this information to the U.S. Department of Agriculture with a recommendation that no changes be made to the number of importer, first handler, or producer seats on the Board. However, the Board recommended elimination of two non-voting wholesaler/retailer positions that have not been filled since 2007.

DATES: *Effective Date:* June 23, 2011.

FOR FURTHER INFORMATION CONTACT: Veronica Douglass, Marketing Specialist, Research and Promotion Branch, Fruit and Vegetable Programs, AMS, U.S. Department of Agriculture, Stop 0244, Room 0632–S, 1400 Independence Avenue, SW., Washington, DC 20250–0244; telephone: 888–720–9917; fax: 202–205–2800; or e-mail: *veronica.douglass@ams.usda.gov*.

SUPPLEMENTARY INFORMATION: This rule is issued under the Mango Promotion, Research, and Consumer Information Order (Order) [7 CFR part 1206]. The Order is authorized by the Commodity Promotion, Research, and Information Act of 1996 (Act) [7 U.S.C. 7411–7425].

Executive Order 12866

The Office of Management and Budget (OMB) has waived the review process required by Executive Order 12866 for this action.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have a retroactive effect.

Section 524 of the Act provides that the Act shall not affect or preempt any other State or Federal law authorizing promotion or research relating to an agricultural commodity.

Under the Act, a person subject to an order may file a petition with the U.S. Department of Agriculture (Department) stating that an order, any provision of an order, or any obligation imposed in connection with an order, is not established in accordance with the law, and requesting a modification of an order or an exemption from an order. Any petition filed challenging an order, any provision of an order, or any obligation imposed in connection with an order, shall be filed within two years after the effective date of an order, provision, or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, the Department will issue a ruling on the petition. The Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have the jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of the entry of the Department's final ruling.

Regulatory Flexibility Analysis and Paperwork Reduction Act

In accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities that would be affected by this rule. The purpose of the RFA is to fit regulatory action to scale on businesses subject to such action, so that small businesses will not be disproportionately burdened.

The Small Business Administration defines small agricultural producers as those having annual receipts of no more than $750,000, and small agricultural service firms as those having annual receipts of no more than $7 million (13 CFR part 121). First handlers, importers, wholesalers, and retailers would be considered agricultural service firms. Currently, fewer than five first handlers and 193 importers are subject to assessment under the Order. The majority of producers would be considered small businesses. The majority of these first handlers and importers would be considered small businesses, while wholesalers and retailers would not.

First handlers and importers who market or import less than 500,000 pounds of mangos annually are exempt from the assessment. Mangos that are exported out of the United States are also exempt from assessment. In addition, domestic producers, foreign producers, wholesalers, and retailers are not subject to assessment under the Order, but such individuals are eligible to serve on the Board along with importers and first handlers.

Section 1206.30(c) of the Order requires that the Board review the volume and geographical distribution of mango production and imports at least once every five years. If warranted, the Board will recommend to the Department that membership on the Board be altered to reflect any changes in the volume and geographical distribution of mango production and imports.

The Order currently provides for a Board of 20 members including eight importers, one first handler, two domestic producers, seven foreign producers, and two non-voting wholesalers and/or retailers. At its November 16, 2010 meeting, the Board reviewed the volume and geographic distribution of mango production and imports from 2006 through 2009. Based on data from U.S. Customs and Border Patrol, the volume of mango imports to the U.S. declined from 666,772,761 pounds in 2006 to 627,271,605 pounds in 2009. The Board's eight importer seats are allocated based on the volume of mangos imported into each of the four Districts defined in the Order. The

current allocation is two seats for District I, three seats for District II, two seats for District III, and one seat for District IV. The percentage of the total mango import volume imported into District I remained at 25 percent from 2006 to 2009. Imports into District II grew from 35 percent of the total in 2006 to 41 percent in 2009. Imports into District III fell from 28 percent of the total in 2006 to 23 percent in 2009. Imports into District IV fell from 12 percent of the total in 2006 to 11 percent in 2009. Much of the domestic mango production was adversely affected by hurricanes during the early 2000s. Accordingly, data provided by the Board shows that in 2006, no assessments were collected on domestic mangos, while in 2009 assessments were collected on 1,539,306 pounds of domestic mangos. After reviewing the data regarding mango imports and domestic production, the Board voted to recommend that no changes be made at this time to the number of importer, first handler, domestic producer, or foreign producer seats; or to the allocation of importer seats among the four districts.

At the same meeting, the Board voted to request elimination of the wholesaler/retailer positions from the Order. These positions were included so that the Board would include members with direct customer sales experience. The Board has made numerous attempts to nominate individuals to those positions; however, wholesalers and retailers are not interested in or do not have the time to serve on the Board. As a result, the two wholesaler/retailer positions have been vacant since 2008. These two positions do not represent assessment payers. If the wholesaler/retailer positions are eliminated, the Board would consist of a total of 18 members including eight importers, one first handler, two domestic producers, and seven foreign producers.

Nominations and appointments to the Board are conducted pursuant to sections 1206.31 and 1206.33 of the Order. Appointments to the Board are made by the Secretary from a slate of nominated candidates. Pursuant to section 1206.31 of the Order, candidates for the importer, first handler, and domestic producer positions are nominated by their peers. Nominations for the foreign producer positions are solicited from foreign mango producer organizations. The Board nominates the wholesaler/retailer members. The Order requires that two nominees be submitted for each vacant position.

In accordance with OMB regulation [5 CFR part 1320], which implements information collection requirements imposed by the Paperwork Reduction Act of 1995 [44 U.S.C. 3501 *et seq.*], there are no new requirements contained in this rule. In fact, a decrease of 0.33 hours per year in the information collection burden for the mango program is expected. The information collection requirements have been previously approved by OMB under OMB control number 0581–0093.

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

Background

The Order, which became effective November 3, 2004, is authorized under the Act and administered by the Board. The Order provides for a 20-member Board consisting of eight importers, one first handler, two domestic producers, seven foreign producers, and two non-voting wholesalers and/or retailers.

Under the Order, the Board administers a nationally coordinated program of promotion, research, and information designed to strengthen the position of mangos in the marketplace and to develop, maintain, and expand the demand for mangos in the United States. The program is financed by an assessment of ½ cent per pound on first handlers and importers who market or import 500,000 pounds or more of mangos annually. Under the Order, first handlers remit assessments directly to the Board, and assessments paid by importers are collected and remitted by U.S. Customs and Border Patrol.

Pursuant to section 1206.30(c) of the Order, at least once in each five-year period, the Board shall review the volume and geographical distribution of mango production and imports and, if warranted, make a recommendation to the Secretary to alter the Board's membership. On November 16, 2010, at its fall meeting, the Board voted to recommend that no changes be made to the importer, first handler, domestic producer, or foreign producer positions, but that the non-voting wholesaler/retailer positions be eliminated. If the wholesaler/retailer positions are eliminated, the Board's membership will be reduced from 20 to 18.

Accordingly, this action will amend the Order by removing the definition of retailer in section 1206.19, the definition of wholesaler in section 1206.24, and references to wholesalers and/or retailers in sections 1206.31 and 1206.32.

A proposed rule concerning this action was published in the **Federal Register** on March 14, 2011 [76 FR 13530]. Copies of the proposed rule were made available on the Internet by the Department and the Office of the Federal Register. In addition, AMS published a press release announcing the comment period. The proposed rule provided a 30-day comment period, which ended April 13, 2011. Twelve comments were received by the deadline.

Summary of Comments

In response to the proposed rule, USDA received 12 comments regarding the proposed amendment of the Order to eliminate two non-voting wholesaler/retailer positions on the Board. Of the 12 comments received, nine supported the proposed amendment and three did not support the proposed amendment.

A total of eight comments in support of the proposed amendment discussed the Board's reasons for requesting elimination of the wholesaler/retailer positions. Seven of the comments cited the potential for conflict of interest created by participation of wholesalers and/or retailers in Board meetings where decisions could be influenced by their business interests with individual Board members.

Five comments in favor of the proposed amendment mentioned the Board's retention of retail account managers who gather input from the retail sector and help the Board to develop appropriate programs. These commenters stated that having a dedicated team of retail account managers is an effective means of communicating with wholesalers and retailers.

Five comments expressed support for the elimination of the wholesaler/retailer positions on the basis that input from wholesalers and/or retailers can be obtained as needed through their ad hoc participation on the Board's committees. The Board's bylaws permit the Board's chairman to appoint committees that may include persons other than Board members. Subject to Board approval, committee chairmen are also permitted to appoint committee members who are not Board members.

Four commenters supported elimination of the wholesaler/retailer positions, stating that past wholesaler/retailer members struggled with the time and travel demands of Board membership and rarely attended Board meetings.

Three comments in favor of the proposed amendment stated that the funds used to service the wholesaler/retailer positions would be better spent on the Board's promotional programs.

One commenter agreed with the proposed rule without providing additional explanation.

Two commenters expressed opposition to the notion that

representation on the Board is linked to the payment of assessments. The Order requires a review of the composition of the Board to be conducted every five years and states that the review is to be based on Board assessment records and statistics from USDA. The number of importer, first handler, and domestic producer seats, as well as the distribution of importer seats, is adjusted as needed based on the volume and geographic distribution of mango production and imports. In addition, the volume of imports for each country of origin is considered in appointments of foreign producer members. Because the volume handled or imported is linked to the value of assessments received by the Board, representation of importers, first handlers, domestic producers and foreign producers is necessarily linked to the payment of assessments. However, that is not the case for the wholesaler/retailer positions.

Two commenters expressed opposition to the proposed elimination of the wholesaler/retailer positions on the grounds that wholesalers and/or retailers could provide valuable insight to the Board. As stated above, the Board's bylaws permit the participation of non-members on the Board's committees. Thus the Board is able to seek input from wholesalers and/or retailers as needed.

One commenter expressed doubt that the Board has made sufficient efforts to secure nominees to fill the wholesaler/retailer positions. As discussed in the proposed rule, the Board has made numerous attempts to nominate individuals to those positions; however, wholesalers and retailers are either not interested in or do not have the time to serve on the Board.

One commenter recommended that wholesalers and/or retailers be given full voting rights on the Board. The question of whether or not wholesaler/retailer members should be permitted to vote is not considered in this rule as it is not relevant given the Board's inability to find wholesalers and/or retailers to serve on the Board. The same commenter also suggested that the Board consider adding consumer members. Currently, all Board meetings are open to the public, and any person has the opportunity to contact the Board at any time. As such, consumer participation in Board activities does not require amendment of the Order.

One comment objecting to the regulation of mangos was outside the scope of this rule.

The Department has considered all of the comments and is not making any changes to the proposed rule.

After consideration of all relevant material presented, the Board's recommendation, public comments and other information, it is hereby found that this rule, as published in the **Federal Register** [76 FR 13530] on March 14, 2011, is consistent with and will effectuate the purpose of the Act.

List of Subjects in 7 CFR Part 1206

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Mango Promotion, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 1206 is amended as follows:

PART 1206—MANGO PROMOTION, RESEARCH, AND INFORMATION ORDER

■ 1. The authority citation for 7 CFR part 1206 continues to read as follows:

Authority: 7 U.S.C. 7411–7425 and 7 U.S.C. 7401.

■ 2. Remove and reserve § 1206.19.

§ 1206.19 [Reserved]

■ 3. Remove and reserve § 1206.24.

§ 1206.24 [Reserved]

■ 4. Amend § 1206.30 by revising paragraph (a) to read as follows:

§ 1206.30 Establishment of the National Mango Promotion Board.

(a) *Establishment of the National Mango Promotion Board.* There is hereby established a National Mango Promotion Board composed of eight importers, one first handler, two domestic producers, and seven foreign producers. The chairperson shall reside in the United States and the Board office shall also be located in the United States.

* * * * *

■ 5. Amend § 1206.31 by removing paragraph (h), and redesignating paragraph (i) as paragraph (h).

■ 6. Revise § 1206.32 to read as follows:

§ 1206.32 Term of office.

The term of office for first handler, importer, domestic producer, and foreign producer members of the Board will be three years, and these members may serve a maximum of two consecutive three-year terms. When the Board is first established, the first handler, two importers, one domestic producer, and two foreign producers will be assigned initial terms of four years; three importers, one domestic producer, and two foreign producers will be assigned initial terms of three years; and three importers and three foreign producers will be assigned initial terms of two years. Thereafter, each of these positions will carry a full three-year term. Members serving initial terms of two or four years will be eligible to serve a second term of three years. Each term of office will end on December 31, with new terms of office beginning on January 1.

Dated: June 16, 2011.

Rayne Pegg,

Administrator.

[FR Doc. 2011–15630 Filed 6–21–11; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0259; Directorate Identifier 2010–NM–196–AD; Amendment 39–16730; AD 2011–13–07]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Model FALCON 7X Airplanes

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

ACTION: Final rule.

SUMMARY: We are superseding an existing airworthiness directive (AD) that applies to the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

Several occurrences of untimely radio-altimeter lock-up have been reported, where the failed radio-altimeter indicated a negative distance to the ground despite the aircraft was flying at medium or high altitude.

A locked radio-altimeter #1 leads to untimely inhibition of warnings that could be displayed along with certain abnormal conditions while the avionic system switches into landing mode during altitude cruise.

* * * * *

[Untimely radio altimeter lock-up] may cause the crew to be unaware of possible system failures that could require urgent crew's actions.

* * * * *

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

DATES: This AD becomes effective July 27, 2011.

ADDRESSES: You may examine the AD docket on the Internet at *http://*

www.regulations.gov or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on March 29, 2011 (76 FR 17364), and proposed to supersede AD 2010–02–02, Amendment 39–16173 (75 FR 1697, January 13, 2010). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

> Several occurrences of untimely radio-altimeter lock-up have been reported, where the failed radio-altimeter indicated a negative distance to the ground despite the aircraft was flying at medium or high altitude.
>
> A locked radio-altimeter #1 leads to untimely inhibition of warnings that could be displayed along with certain abnormal conditions while the avionic system switches into landing mode during altitude cruise.
>
> * * * * *
>
> [Untimely radio altimeter lock-up] may cause the crew to be unaware of possible system failures that could require urgent crew's actions.
>
> To address this unsafe condition, [EASA] AD 2009–0208 was issued on 13 October 2009 [which corresponds with FAA AD 2010–02–02]. It mandated application of a new abnormal Airplane Flight Manual (AFM) procedure when radio-altimeter #1 lock-up occurs and prohibited dispatch of the aeroplane with any radio-altimeter inoperative.
>
> Since AD 2009–0208 was issued, Easy avionics load 10 has been developed with change M0566 or Service Bulletin (SB) Falcon 7X n°100 that brings new features to display a ''RA miscompare'' flag on both Primary Display Units (PDU) and accepts a commanded system reversion to the correct radio-altimeter output.
>
> EASA AD 2009–0208R1 is issued to allow not deactivating radio-altimeter #1 in case lock-up conditions occur in flight for aeroplanes on which M0566 or SB Falcon 7X n°100 has been embodied.

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

Comments

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

Conclusion

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

Differences Between This AD and the MCAI or Service Information

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

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

Costs of Compliance

We estimate that this AD will affect about 24 products of U.S. registry.

The actions that are required by AD 2010–02–02 and retained in this AD take about 1 work-hour per product, at an average labor rate of $85 per work-hour. Based on these figures, the estimated cost of the currently required actions is $85 per product.

We estimate that it will take about 1 work-hour per product to comply with the new basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $2,040, or $85 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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

Examining the AD Docket

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Amendment 39–16173 (75 FR 1697, January 13, 2010) and adding the following new AD:

2011–13–07 Dassault Aviation: Amendment 39–16730. Docket No. FAA–2011–0259; Directorate Identifier 2010–NM–196–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective July 27, 2011.

Affected ADs

(b) This AD supersedes AD 2010–02–02, Amendment 39–16173.

Applicability

(c) This AD applies to Dassault Aviation Model FALCON 7X airplanes, certificated in any category, all serial numbers.

Subject

(d) Air Transport Association (ATA) of America Code 34: Navigation.

Reason

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

Several occurrences of untimely radio-altimeter lock-up have been reported, where the failed radio-altimeter indicated a negative distance to the ground despite the aircraft was flying at medium or high altitude.

A locked radio-altimeter #1 leads to untimely inhibition of warnings that could be displayed along with certain abnormal conditions while the avionic system switches into landing mode during altitude cruise.

* * * * *

[Untimely radio altimeter lock-up] may cause the crew to be unaware of possible system failures that could require urgent crew's actions.

* * * * *

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Restatement of Requirements of AD 2010–02–02, With Revised Affected Airplanes

(g) For airplanes on which modification M0566 or Dassault Service Bulletin Falcon 7X–100 has not been accomplished: Within 14 days after January 28, 2010 (the effective date of AD 2010–02–02), revise the Limitations Section of the Dassault Falcon 7X Airplane Flight Manual (AFM) to include the following statement. This may be done by inserting a copy of this AD in the AFM.

''If radio-altimeter #1 lock-up conditions occur in flight, power off radio-altimeter #1, in accordance with the instructions of Falcon 7X AFM procedure 3–140–65.

Dispatch of the airplane with any radio-altimeter inoperative is prohibited.''

Note 1: When a statement identical to that in paragraph (g) of this AD has been included in the general revisions of the AFM, the general revisions may be inserted into the AFM, and the copy of this AD may be removed from the AFM.

New Requirements of This AD

(h) For airplanes on which M0566 or Dassault Service Bulletin Falcon 7X–100 has been accomplished: Within 14 days after the effective date of this AD, revise the Limitations Section of the Dassault Falcon 7X AFM to include the following statement. This may be done by inserting a copy of this AD in the AFM. Doing this revision terminates the requirements of paragraph (g) of this AD.

''If radio-altimeter #1 lock-up conditions occur in flight, revert to the correct radio-altimeter output, in accordance with the instructions of Falcon 7X AFM procedure 3–140–65B and 3–140–70A.

Dispatch of the airplane with any radio-altimeter inoperative is prohibited.''

Note 2: When a statement identical to that in paragraph (h) of this AD has been included in the general revisions of the AFM, the general revisions may be inserted into the AFM, and the copy of this AD may be removed from the AFM.

FAA AD Differences

Note 3: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, 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 International Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149. Information may be e-mailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. 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. The AMOC approval letter must specifically reference this AD.

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

Related Information

(j) Refer to MCAI European Aviation Safety Agency (EASA) Airworthiness Directive 2009–0208R1, dated June 2, 2010, for related information.

Material Incorporated by Reference

(k) None.

Issued in Renton, Washington, on June 14, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–15368 Filed 6–21–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0116; Airspace Docket No. 11–ANE–1]

Establishment of Class E Airspace; Brunswick, ME

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E Airspace at Brunswick, ME, to accommodate the additional airspace needed for the Standard Instrument Approach Procedures developed for Brunswick Executive Airport. This enhances the safety and airspace management of Instrument Flight Rules (IFR) operations at the airport. This action also corrects errors in the legal description published as a proposed rule in the **Federal Register** on March 18, 2011.

DATES: Effective 0901 UTC, August 25, 2011. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

History

On March 18, 2011, the FAA published in the **Federal Register** a notice of proposed rulemaking to establish Class E airspace at Brunswick Executive Airport, Brunswick, ME (75 FR 14824) Docket No. FAA–2011–0116. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received. Subsequent to publication, a typographical error was found in the controlled airspace radius mileage. This action will make the correction.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9U dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR Part 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 establishes Class E airspace extending upward from 700 feet above the surface at Brunswick, ME to provide controlled airspace required to support the standard instrument approach procedures developed for Brunswick Executive Airport. This action is necessary for the safety and management of IFR operations at the airport. Brunswick Executive Airport uses the same facilities as the former Brunswick Naval Air Station (NAS), which closed in September 2010 (see 75 FR 57848).

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

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

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace at Brunswick, ME.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, effective September 15, 2010, is amended as follows:

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

* * * * *

ANE ME E5 Brunswick, ME [New]

Brunswick Executive Airport, ME
(Lat. 43°53′32″N., long. 69°56′19″ W.)

That airspace extending upward from 700 feet above the surface within a 7.7-mile radius of Brunswick Executive Airport.

Issued in College Park, Georgia, on June 2, 2011.

Mark D. Ward,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2011–15305 Filed 6–21–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0252; Airspace Docket No. 11–ANM–5]

Modification of Class E Airspace; Newcastle, WY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace at Newcastle, WY, to accommodate aircraft using the Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures at Mondell Field Airport. This improves the safety and management of Instrument Flight Rules (IFR) operations at the airport. The airport name also is being changed to Mondell Field Airport.

DATES: Effective date, 0901 UTC, August 25, 2011. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue, SW., Renton, WA 98057; telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

History

On April 12, 2011, the FAA published in the **Federal Register** a notice of proposed rulemaking to amend controlled airspace at Newcastle, WY (76 FR 20281). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9U dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in that Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by amending Class E airspace extending upward from 700 feet above the surface, at Mondell Field Airport, to accommodate IFR aircraft using the RNAV (GPS) standard instrument approach procedures at the airport. This action is necessary for the safety and management of IFR operations. The airport name is being changed from Mondell Field, to Mondell Field Airport, Newcastle, WY. With the exception of minor corrections made to the regulatory text at the request of the FAA's Aeronautical Products Office, this rule is the same as that proposed in the NPRM.

The FAA has determined this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT

Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106 discusses the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes additional controlled airspace at Mondell Field Airport, Newcastle, WY.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR Part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM WY E5 Newcastle, WY [Modified]

Mondell Field Airport, WY
(Lat. 43°53′08″ N., long. 104°19′05″ W.)
Ellsworth AFB, SD
(Lat. 44°08′42″ N., long. 103°06′13″ W.)

That airspace extending upward from 700 feet above the surface within 4 miles northeast and 8.3 miles southwest of the Mondell Field Airport 154° and 334° bearings extending from 5.3 miles northwest to 16.1 miles southeast of the airport; that airspace extending upward from 1,200 feet above the surface bounded on the north by the north edge of V–86, on the east by a 45.6-mile radius of Ellsworth AFB, on the south by the south edge of V–26, on the west by a line 4.3 miles west of and parallel to the Mondell Field Airport 360° bearing and 180° bearing; that airspace extending upward from 7,000 feet MSL bounded on the north by the north edge of V–26, on the east by a 45.6-mile radius of Ellsworth AFB, on the south by the south edge of V–26, on the west by a line 4.3 miles west of and parallel to the Mondell Field Airport 360° bearing and 180° bearing.

Issued in Seattle, Washington on June 13, 2011.

John Warner,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2011–15375 Filed 6–21–11; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 34–64678; File No. S7–24–11]

Temporary Exemptions and Other Temporary Relief, Together With Information on Compliance Dates for New Provisions of the Securities Exchange Act of 1934 Applicable to Security-Based Swaps

AGENCY: Securities and Exchange Commission.

ACTION: Exemptive order.

SUMMARY: The Securities and Exchange Commission (''Commission'') is issuing an exemptive order granting temporary exemptive relief and other temporary relief from compliance with certain provisions of the Securities Exchange Act of 1934 (''Exchange Act'') concerning security-based swaps. The Commission also is providing guidance regarding compliance with other provisions of the Exchange Act concerning security-based swaps that were amended or added by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (''Dodd-Frank Act'') and requesting comments on such guidance and the temporary relief granted.

DATES: This exemptive order is effective June 15, 2011. Comments must be received on or before July 6, 2011.

ADDRESSES: Comments may be submitted, identified by File Number S7–24–11, by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/interp.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number S7–24–11 on the subject line; or
- Use the Federal Rulemaking Portal (*http://www.regulations.gov*). Follow the instructions for submitting comments.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090. All submissions should refer to File Number S7–24–11. This file number should be included on the subject line if e-mail is used. To help us 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/proposed.shtml*). Comments are also 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 a.m. and 3 p.m. All comments received will be posted without charge; the Commission does not edit personal identifying information from submissions. You should only submit information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Jack Habert, Attorney Fellow, at (202) 551–5063; Leah Drennan, Attorney-Adviser, at (202) 551–5507; or Ann McKeehan, Attorney-Adviser, at (202) 551–5797, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–7010.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction and Background.
II. Discussion.
A. Clearing for Security-Based Swaps.
B. Security-Based Swap Execution Facilities.
C. Segregation of Collateral in Security-Based Swaps.
D. Security-Based Swap Antifraud Provisions.
E. Position Limits for Security-Based Swaps.
F. Reporting of Security-Based Swaps.
i. Public Availability of Security-Based Swap Data.
ii. Security-Based Swap Data Repositories.

iii. Reporting and Recordkeeping for Security-Based Swaps.
G. Registration and Regulation of Security-Based Swap Dealers and Major Security-Based Swap Participants.
H. Registration of Clearing Agencies for Security-Based Swaps.
I. Other Amendments to the Federal Securities Laws Relating to Security-Based Swaps.
J. Section 29(b) of the Exchange Act.
III. Solicitation of Comments.
IV. Temporary Exemptions and Other Temporary Relief

I. Introduction and Background.

On July 21, 2010, President Barack Obama signed the Dodd-Frank Act into law.[1] The Dodd-Frank Act was enacted, among other reasons, to promote the financial stability of the United States by improving accountability and transparency in the financial system.[2] The recent financial crisis demonstrated the need for enhanced regulation of the over-the-counter (''OTC'') derivatives markets, which have experienced dramatic growth in recent years [3] and are capable of affecting significant sectors of the U.S. economy.[4] Title VII of the Dodd-Frank Act (''Title VII'') establishes a regulatory regime applicable to the OTC derivatives markets by providing the Commission and the Commodity Futures Trading Commission (''CFTC'') with the tools to oversee these heretofore largely unregulated markets. The Dodd-Frank Act provides that the CFTC will regulate ''swaps,'' the Commission will regulate ''security-based swaps,'' and the CFTC and the Commission will jointly regulate ''mixed swaps.'' [5]

Title VII amends the Exchange Act [6] to substantially expand the regulation of the security-based swap (''SB swap'') markets, establishing a new regulatory framework within which such markets can continue to evolve in a more transparent, efficient, fair, accessible, and competitive manner.[7] The Dodd-Frank Act amendments to the Exchange Act impose, among other requirements, the following: (1) Registration and comprehensive oversight of SB swap dealers (''SBSDs'') and major SB swap participants (''MSBSPs'' and, collectively with SBSDs, ''SBS Entities''); [8] (2) reporting of SB swaps to a registered SB swap data repository (''SDR''), to the Commission, and to the public; [9] (3) clearing of SB swaps through a registered clearing agency or through a clearing agency that is exempt from registration [10] if such SB swaps are of a type that the Commission determines is required to be cleared, unless an exemption or exception from such mandatory clearing applies; [11] and (4) if an SB swap is subject to the clearing requirement,[12] execution of the SB swap transaction on an exchange, on an SB swap execution facility (''SB SEF'') registered under section 3D of the Exchange Act,[13] or on an SB SEF that has been exempted from registration by the Commission under section 3D(e) of the Exchange Act,[14] unless no SB SEF or exchange makes such SB swap available for trading.[15] Title VII also amends the Exchange Act and the Securities Act of 1933 [16] (''Securities Act'') to include ''security-based swaps'' in the definition of ''security'' for purposes of those statutes.[17] As a result, ''security-based swaps'' will be subject to the provisions of the Securities Act and the Exchange Act and the rules thereunder applicable to ''securities.'' [18] The Commission has proposed exemptions [19] under the Securities Act, the Exchange Act, and the Trust Indenture Act of 1939 [20] (''Trust Indenture Act'') for SB swaps issued by certain clearing agencies satisfying certain conditions.[21] In addition, the Commission will take other actions to address certain SB swaps, such as providing guidance regarding—and where appropriate, temporary relief from—the various pre-Dodd Frank Act provisions that would otherwise apply to SB swaps on July 16, 2011, as well as extending existing temporary rules under the Securities Act, the Exchange

[1] The Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[2] *Id.* at preamble.

[3] From their beginnings in the early 1980s, the notional value of these markets has grown to almost $600 trillion globally. *See* Monetary and Econ. Dep't, Bank for Int'l Settlements, *Triennial and Semiannual Surveys—Positions in Global Over-the-Counter (OTC) Derivatives Markets at End-June 2010* (Nov. 2010), *available at http://www.bis.org/publ/otc_hy1011.pdf.*

[4] *See* 156 Cong. Rec. S5878 (daily ed. July 15, 2010) (statement of Sen. Dodd).

[5] Section 712(d) of the Dodd-Frank Act provides that the Commission and the CFTC, in consultation with the Board of Governors of the Federal Reserve System, shall further define the terms ''swap,'' ''security-based swap,'' ''swap dealer,'' ''security-based swap dealer,'' ''major security-based swap participant,'' ''eligible contract participant,'' and ''security-based swap agreement.'' These terms are defined in sections 721 and 761 of the Dodd-Frank Act and the Commission and the CFTC have proposed to further define these terms in proposed joint rulemaking. *See* Further Definition of ''Swap,'' ''Security-Based Swap,'' and ''Security-Based Swap Agreement''; Mixed Swaps; Security-Based Swap Agreement Recordkeeping, 76 FR 29818 (May 23, 2011); Further Definition of ''Swap Dealer,'' ''Security-Based Swap Dealer,'' ''Major Swap Participant,'' ''Major Security-Based Swap Participant'' and ''Eligible Contract Participant,'' 75 FR 80174 (Dec. 21, 2010) (''Entity Definitions Release'').

[6] 15 U.S.C. 78a *et seq.*

[7] *See generally* subtitle B of Title VII. Citations to provisions of the Exchange Act in this Order refer to the numbering of those provisions after the amendments made by the Dodd-Frank Act, except as otherwise provided.

[8] As required by the Dodd-Frank Act, the Commission will propose rules regarding the registration of SBS Entities and a process for revocation of such registration. *See* section 15F of the Exchange Act, 15 U.S.C. 78o–10.

[9] *See* section 3(a)(75) of the Exchange Act, 15 U.S.C. 78c(a)(75) (defining the term ''security-based swap data repository''). The registration of an SDR and the reporting of SB swaps are the subject of separate Commission rulemakings. *See* Security-Based Swap Data Repository Registration, Duties, and Core Principles, 75 FR 77305 (Dec. 10, 2010), corrected at 75 FR 79320 (Dec. 20, 2010) and 76 FR 2287 (Jan. 13, 2011); Regulation SBSR—Reporting and Dissemination of Security-Based Swap Information, 75 FR 75207 (Dec. 2, 2010).

[10] *See* Clearing Agency Standards for Operation and Governance, 76 FR 14472 (Mar. 16, 2011). The Commission has proposed rules regarding registration of clearing agencies and standards for the operation and governance of clearing agencies, including rules that would exempt certain SBSDs and SB SEFs from the definition of a clearing agency.

[11] *See* section 3C(a)(1) of the Exchange Act, 15 U.S.C. 78c–3(a)(1). The Commission has proposed rules regarding the manner in which clearing agencies provide information to the Commission about SB swaps that the clearing agency plans to accept for clearing and that would, in turn, be used by the Commission in determining whether such SB swaps are required to be cleared. *See* Process for Submissions for Review of Security-Based Swaps for Mandatory Clearing and Notice Filing Requirements for Clearing Agencies; Technical Amendments to Rule 19b–4 and Form 19b–4 Applicable to All Self-Regulatory Organizations, 75 FR 82489 (Dec. 30, 2010).

[12] *See* section 3C(g) of the Exchange Act, 15 U.S.C. 78c–3(g) (providing an exception to the clearing requirement for certain persons).

[13] 15 U.S.C. 78c–4.

[14] 15 U.S.C. 78c–4(e).

[15] *See* section 3C(g) of the Exchange Act, 15 U.S.C. 78c–3(g). *See* section 3C(h) of the Exchange Act, 15 U.S.C. 78c–3(h). *See also* section 3(a)(77) of the Exchange Act, 15 U.S.C. 78c(77) (defining the term ''security-based swap execution facility''). The Commission has proposed an interpretation of the definition of ''security-based swap execution facility'' and has proposed rules to implement registration requirements, duties, and core principles for SB SEFs. *See* Registration and Regulation of Security-Based Swap Execution Facilities, 76 FR 10946 (Feb. 28, 2011).

[16] 15 U.S.C. 77a *et seq.*

[17] *See* sections 761(a)(2) and 768(a)(1) of the Dodd-Frank Act (amending sections 3(a)(10) of the Exchange Act, 15 U.S.C. 78c(a)(10), and 2(a)(1) of the Securities Act, 15 U.S.C. 77b(a)(1), respectively).

[18] The Commission has considered similar issues raised by the treatment of credit default swaps as securities in connection with taking action in the past to facilitate clearing of certain credit default swaps (''CDS'') by clearing agencies functioning as central counterparties (''CCPs''). *See infra* notes 222 and 223.

[19] *See* Exemptions for Security-Based Swaps Issued by Certain Clearing Agencies, Securities Act Release No. 9222, Exchange Act Release No. 64639, Trust Indenture Act Release No. 2474 (June 9, 2011) (''Proposed Cleared SB Swap Exemptions'').

[20] 15 U.S.C. 77aaa *et seq.*

[21] *See* discussion *infra* note 223.

Act, and the Trust Indenture Act for certain SB swaps.[22]

The provisions of Title VII generally are effective on July 16, 2011 (360 days after enactment of the Dodd-Frank Act, referred to herein as the ''Effective Date''), unless a provision requires a rulemaking. Specifically, if a Title VII provision requires a rulemaking, such provision will not necessarily go into effect on the Effective Date, but instead will go into effect ''not less than'' 60 days after publication of the related final rule or on July16, 2011, whichever is later.[23] A substantial number of Title VII provisions require a rulemaking and thus will not go into effect on the Effective Date. A number of Title VII provisions also expressly (or implicitly) apply only to ''registered'' persons. Until the related registration processes for such persons have been established by final Commission rules, and such persons have become registered pursuant to such rules, they will not be required to comply with these Title VII provisions.[24] Other provisions of Title VII impose requirements that require compliance by market participants as a result of, or in response to, Commission action other than rulemaking and thus do not impose a compliance obligation upon market participants in the absence of such Commission action.

In addition, Title VII provides the Commission with flexibility to establish effective dates beyond the minimum 60 days specified therein for Title VII provisions that require a rulemaking.[25] Furthermore, as with other rulemakings under the Exchange Act, the Commission may set compliance dates (which may be later than the effective dates) for rulemakings under the Title VII amendments to the Exchange Act. Together, this provides the Commission with the ability to sequence the implementation of the various Title VII requirements in a way that effectuates the policy goals of Title VII while minimizing unnecessary disruption or costs.

Title VII also includes certain provisions that authorize or direct the Commission to take specified action that, once undertaken, may impose compliance obligations upon market participants.[26] These provisions will become effective on the Effective Date, but, by their plain language, pertain to Commission action. Accordingly, these provisions do not require compliance by market participants on the Effective Date unless the relevant Commission action already has been undertaken. The Commission does not expect to complete all of the rulemaking it is directed to carry out pursuant to these provisions prior to the Effective Date.

In furtherance of the Dodd-Frank Act's stated objective of promoting financial stability in the U.S. financial system, the Commission intends to move forward expeditiously with the implementation of the new SB swap requirements in an efficient manner, while minimizing unnecessary disruption and costs to the markets. The Commission recognizes that many market participants will find compliance with Title VII to be a substantial undertaking. SB swap markets already exist, are global in scope, and have generally grown in the absence of regulation in the United States and elsewhere. In addition, the SB swap markets are interconnected with other financial markets, including the traditional securities markets. In order to comply with Title VII provisions and related rules, the Commission recognizes that market participants will need additional time to acquire and configure necessary systems or to modify existing practices and systems, engage and train necessary staff, and develop and implement necessary policies and procedures.[27] Furthermore, some of these changes cannot be finalized until certain rules are effective. Accordingly, it is necessary or appropriate to defer some of these tasks until certain rules are effective, as more fully described below.

In order to effectuate the purposes of Title VII, and in response to comments received from market participants,[28] the Commission is providing guidance as to the provisions of the Exchange Act added by Title VII with which industry compliance will be required as of the Effective Date.[29]

In addition, and for the reasons discussed in this Order, the Commission

[22] *See* SEC Announces Steps to Address One-Year Effective Date of Title VII of Dodd-Frank Act, *available at http://www.sec.gov/news/press/2011/2011–125.htm* (June 10, 2011).

[23] *See* section 774 of the Dodd-Frank Act, 15 U.S.C. 77b note.

[24] *See, e.g.,* sections 15F(e)(1) of the Exchange Act, 15 U.S.C. 78o–10(e)(1) (capital and margin requirements); 15F(f)(1) (reporting and recordkeeping); 15F(h)(1) (business conduct standards).

[25] *See id.* (specifying that the effective date for a provision requiring a rulemaking is ''not less than 60 days after publication of the final rule or regulation implementing such provision'').

[26] *See, e.g.,* section 3D(f) of the Exchange Act, 15 U.S.C. 78c–4(f) (requiring the Commission to prescribe rules governing the regulation of SB SEFs). Certain of these provisions relate to the CFTC or another government agency in addition to, or instead of, the Commission.

[27] The Commission expects that it will not, by July 16, 2011, have completed implementing Title VII. As a result, the Commission believes it would not be reasonable to require market participants to put systems in place or hire personnel based on a regulatory scheme that is not fully in place. To require otherwise, depending on the content of the final rules, might require these entities to incur costs to change their systems again in a relatively short period of time.

[28] The Commission has received comments from a wide range of commenters inquiring as to the effective dates and related compliance dates of certain provisions and requesting that the Commission propose a compliance schedule for the statutory provisions of subtitle B of Title VII and the rules being promulgated thereunder. *See, e.g.,* letter from American Bankers Association, Financial Services Roundtable, Futures Industry Association, Institute of International Bankers, International Swaps and Derivatives Association, Investment Company Institute, Securities Industry and Financial Markets Association, U.S. Chamber of Commerce (June 10, 2011) (''Trade Association Letter''); letter from Stephen Merkel, Chairman, Wholesale Markets Brokers' Association Americas (June 3, 2010) (''WMBA Letter''); letter from Richard M. Whiting, Executive Director and General Counsel, Financial Services Roundtable (May 12, 2011); letter from Andrew Downes, Managing Director, and James B. Fuqua, Managing Director, UBS Securities LLC (Feb. 7, 2011); letter from Craig S. Donohue, CME Group Inc. (Jan. 18, 2011); letter from R. Glenn Hubbard, Co-Chair, John L. Thornton, Co-Chair, and Hal S. Scott, Director, the Committee on Capital Markets Regulation (Jan. 18, 2011) (''Committee on Capital Markets Regulation Letter''); letter from Larry E. Thompson, General Counsel, the Depository Trust & Clearing Corporation (Jan 18, 2011) (''DTCC Letter''); letter from Mr. James Hill, Managing Director, Morgan Stanley (Nov. 1, 2010) (''Morgan Stanley Letter'').

In addition, many letters from market participants have advocated for a phased-in approach to compliance with the requirements of Title VII. *See, e.g.,* WMBA Letter (suggesting a ''progression'' of finalization of specific Title VII rules); Committee on Capital Markets Regulation Letter (stating that ''the reporting and recordkeeping requirements should be implemented gradually over time''); letter from Financial Services Forum, Futures Industry Association, International Swaps and Derivatives Association, and Securities Industry and Financial Markets Association (May 4, 2011) (stating that ''[t]he Commissions should phase in requirements based on the state of readiness of each particular asset class''); letter from G14 Member dealers and others (Mar. 31, 2011) (suggesting a ''phased-in implementation schedule''); letter from Richard H. Baker, President & Chief Executive Officer, Managed Funds Association (Mar. 24, 2011) (recommending ''milestones for clearing access and voluntary clearing with a phase-in period before clearing becomes mandatory''); DTCC Letter (recommending a ''phased-in'' approach to implementation of reporting requirements under Regulation SBSR); Morgan Stanley Letter (urging the Commission and the CFTC ''to phase in the clearing, execution and other requirements product-by-product over time'').

Some of the commenters cited above addressed issues regarding effective dates, compliance, and implementation that will be addressed by other action to be taken the Commission. *See supra* note 22 and accompanying text.

[29] While this release provides guidance with respect to the provisions of the Exchange Act added by Title VII, as indicated above, the Commission will take other actions to address SB swaps under various provisions of the Federal securities laws. *See supra* note 22 and accompanying text. In addition, after proposing all of the key rules under Title VII, the Commission intends to consider publishing a detailed implementation plan in order to enable the Commission to move forward expeditiously with the roll-out of the new SB swap requirements in an efficient manner, while minimizing unnecessary disruption and costs to the markets. *Id.*

is granting temporary exemptive and other relief that is necessary or appropriate in the public interest, and consistent with the protection of investors, from compliance with certain of those provisions of the Exchange Act with which compliance would otherwise be required as of the Effective Date. Generally, section 36 of the Exchange Act authorizes the Commission to conditionally or unconditionally exempt, by rule, regulation, or order, any person, security, or transaction (or any class or classes of persons, securities, or transactions) from any provision or provisions of the Exchange Act or any rule or regulation thereunder, to the extent such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.[30] This exemptive authority is not available for certain specified provisions of the Exchange Act that relate to SB swaps.[31] Where such exemptive authority is not provided, the Commission is using other available authority to provide appropriate temporary relief.

II. Discussion

A. Clearing for Security-Based Swaps

Section 3C of the Exchange Act, added by section 763(a) of the Dodd-Frank Act, generally provides that, if an SB swap is required to be cleared, it is unlawful for any person to engage in such SB swap unless that person submits such SB swap for clearing to a clearing agency that is registered under the Exchange Act or to a clearing agency that is exempt from registration under the Exchange Act.[32] Table A below lists each provision of section 3C of the Exchange Act and identifies those with which compliance will be required on the Effective Date and those with which compliance will be triggered by registration of a person as a clearing agency, adoption of final rules, or other action by the Commission.[33] For the provisions with which compliance will be required on the Effective Date, Table A notes whether temporary relief from compliance is granted. The rationale and duration for such relief is explained in the text following the table. The table also includes provisions that authorize or direct the Commission to take specified action that, once undertaken, may impose compliance obligations upon market participants.[34] Unless otherwise noted in the table below, these provisions do not require compliance by market participants on the Effective Date.

TABLE A—CLEARING FOR SECURITY-BASED SWAPS—COMPLIANCE DATES

Exchange act section[35]	Compliance date		Authorizes/directs commission action[36]	Relief granted
	Upon effective date (July 16, 2011)	Upon registration, publication of final rules, or other commission action[37]		
3C(a)(1): In general—standard for clearing		✓		N/A.[38]
3C(a)(2): In general—open access		✓		N/A.[39]
3C(b)(1): Commission review—Commission-initiated review			✓	N/A.
3C(b)(2)(A) and (B): Commission review—swap submission		✓		N/A.[40]
3C(b)(2)(C): Commission review—swap submission			✓	N/A.
3C(b)(3): Commission review—deadline			✓	N/A.
3C(b)(4): Commission review—determination			✓	N/A.
3C(b)(5): Commission review—rules			✓	N/A.
3C(c): Stay of clearing requirement			✓	N/A.
3C(d): Prevention of evasion			✓	N/A.
3C(e)(1): Reporting transition rules—pre-enactment SB swaps			✓	Yes.[41]
3C(e)(2): Reporting transition rules—post-enactment SB swaps			✓	N/A.[42]
3C(f)(1): Clearing transition rules		✓		N/A.[43]
3C(f)(2): Clearing transition rules		✓		N/A.[44]
3C(g)(1)–(2), (4): Exceptions—in general; option to clear; treatment of affiliates.		✓		N/A.[45]
3C(g)(3)(A): Exceptions —financial entity definition—in general		✓		N/A.[46]
3C(g)(3)(B): Exceptions—financial entity definition—exclusion			✓	N/A.
3C(g)(5)(A): Exceptions—election of counterparty—SB swaps required to be cleared.		✓		N/A.
3C(g)(5)(B): Exceptions—election of counterparty—SB swaps not required to be cleared.	✓			Yes.
3C(g)(6): Exceptions—abuse of exception			✓	N/A.
3C(h): Trade execution		✓		N/A.
3C(i): Board approval		✓		N/A.[47]
3C(j)(1)—(2): Designation of chief compliance officer—in general; duties.		✓		Yes.[48]
3C(j)(3): Designation of chief compliance officer—annual reports.		✓		N/A.

As indicated in Table A, the Commission is providing temporary exemptive relief from compliance with section 3C(e)(1) of the Exchange Act[49]

[30] 15 U.S.C. 78mm.

[31] *See* section 36(c) of the Exchange Act, 15 U.S.C. 78mm(c) (limiting the Commission's exemptive authority with respect to certain provisions of the Exchange Act added by Title VII, such as sections 13A, 15F, and 17A(g) through (l) of the Exchange Act, 15 U.S.C. 78m–1, 78o–10, and 78q–1(g) through (l)). The Commission notes that the Securities Act provides for exemptive authority to be exercised through rulemaking and, as a result, this Order does not provide for any exemptive action with respect to the Securities Act.

[32] 15 U.S.C. 78c–3.

[33] *Id.*

[34] *See supra* note 26 and accompanying text.

[35] References to section 3C of the Exchange Act in this table are to 15 U.S.C. 78c–3.

[36] These provisions do not require compliance by market participants on the Effective Date, unless the relevant Commission action already has been undertaken. *See supra* note 26 and accompanying text.

[37] A number of Title VII provisions expressly (or implicitly) apply only to ''registered'' persons. Until the related registration processes for such persons have been established by final Commission rules, and such persons have become registered pursuant to such rules, they will not be required to comply with these Title VII provisions. If a Title VII provision requires a rulemaking, such provision will not necessarily go into effect on the Effective Date, but instead will go into effect ''not less than'' 60 days after publication of the related final rule or on July 16, 2011, whichever is later. *See* section 774 of the Dodd-Frank Act, 15 U.S.C. 77b note.

[38] Section 3C(b)(5) of the Exchange Act, 15 U.S.C. 78c–3(b)(5), requires the Commission to ''adopt rules for a clearing agency's submission for review * * * of a security-based swap, or a group, category, type, or class of [SB swaps], that it seeks to accept for clearing.''

[39] Section 3C(a)(2) of the Exchange Act, 15 U.S.C. 78c–3(a)(2), is applicable to ''rules of a clearing agency described in [section 3C(a)(1) of the Exchange Act, 15 U.S.C. 78c–3(a)(1)].'' The clearing agencies described in section 3C(a)(1) of the Exchange Act, 15 U.S.C. 78c–3(a)(1), are required to be registered, or exempt from registration, and clearing SB swaps subject to the clearing requirement. As a result, the requirements of section 3C(a)(2) of the Exchange Act, 15 U.S.C. 78c–3, will not be triggered until a clearing agency is registered or exempt from registration and also is clearing SB swaps that are subject to the clearing requirement. Three entities will be deemed registered on the Effective Date. *See* discussion *infra* part 0. However, no SB swaps will be subject to the clearing requirement on the Effective Date.

[40] Section 3C(b)(2)(B) of the Exchange Act, 15 U.S.C. 78c–3(b)(2)(B), states in part that SB swaps ''listed for clearing by a clearing agency as of the date of enactment of [section 3C(b) of the Exchange Act, 15 U.S.C. 78c–3(b)], shall be considered submitted to the Commission.'' However, pursuant to section 3C(b)(3) of the Exchange Act, 15 U.S.C. 78c–3(b)(3), a clearing agency may agree to extend the time for action required under the section. The relevant clearing agencies have agreed to an extension of the deadline for a determination by the Commission ''until 90 days after the Commission has published final rules governing the process by which SB swaps shall be submitted to the Commission for a clearing determination.'' Until the rulemaking is completed, therefore, no SB swaps will be considered submitted. *See* letter from Lisa Dunsky, Chicago Mercantile Exchange Inc., to Robert Cook, Director, Division of Trading and Markets, Commission (Aug. 26, 2010); letter from Thomas Book, Eurex Clearing AG, to Robert Cook, Director, Division of Trading and Markets, Commission (Aug. 19, 2010); and letter from Trabue Bland, regarding ICE Trust U.S. LLC and ICE Clear Europe Limited, to Robert Cook, Director, Division of Trading and Markets, Commission (Sept. 2, 2010).

[41] The Commission has proposed rules pursuant to this provision. *See infra* note 172.

[42] The Commission has proposed rules pursuant to this provision. *See* Regulation SBSR—Reporting and Dissemination of Security-Based Swap Information, *supra* note 9 (providing by rule a deadline by which post-enactment SB swaps must be reported).

[43] Because the exemption from the clearing requirement in this provision requires the reporting of SB swaps pursuant to section 3C(e)(1) of the Exchange Act, 15 U.S.C. 78c–3(e)(1), market participants cannot comply with this provision until final rules have been adopted pursuant to such section 3C(e)(1).

for market participants with reporting obligations under section 13A of the Exchange Act.[50]

Section 3C(e)(1) of the Exchange Act requires the Commission to adopt rules that provide that ''[s]ecurity-based swaps entered into before the date of enactment of this section [('pre-enactment SB swaps')] shall be reported to a registered security-based swap data repository or the Commission no later than 180 days after the effective date of [section 3C of the Exchange Act].'' [51] Section 3C of the Exchange Act becomes effective on July 16, 2011, and 180 days after that date is January 12, 2012.

The Commission is exercising its authority under section 36 of the Exchange Act [52] to exempt any person from having to report any pre-enactment SB swaps as set forth in the rules adopted by the Commission pursuant to section 3C(e)(1) of the Exchange Act [53] until six (6) months after an SDR that is capable of accepting the asset class of the pre-enactment SB swaps is registered by the Commission. The Commission finds that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors, because, even after an SDR is registered, market participants will need additional time to establish connectivity and develop appropriate policies and procedures to be able to deliver information to the registered SDR. Therefore, under this exemption, no person will be required to report a pre-enactment SB swap in an asset class until six (6) months after an SDR that is capable of accepting SB swaps in that asset class has registered with the Commission.[54]

The Commission also is exercising its authority pursuant to section 36 of the Exchange Act to grant a temporary exemption from section 3C(g)(5)(B) of the Exchange Act.[55] Section 3C(g)(5)(B) of the Exchange Act [56] permits a counterparty to an SB swap that is not subject to the mandatory clearing requirement to elect to clear its SB swap with an SBS Entity. The Commission finds that it is necessary or appropriate in the public interest, and consistent with the protection of investors to grant a temporary exemption to SBS Entities from section 3C(g)(5)(B) of the Exchange Act [57] because the Commission understands that there are currently no CCPs offering customer clearing of SB swaps and additional action by the Commission will be necessary to address segregation and other customer protection issues. Therefore, under this exemption, section 3C(g)(5)(B) of the Exchange Act [58] will not apply until the earliest compliance date set forth in any of the final rules regarding section 3C(b) of the Exchange Act.[59]

In addition, the Commission is exercising its authority pursuant to section 36 of the Exchange Act to grant temporary exemptions from sections 3C(j)(1) and (2) of the Exchange Act.[60] Section 3C(j)(1) of the Exchange Act [61] requires that each registered clearing agency designate an individual to serve as a chief compliance officer. The chief compliance officer will be required to comply with the duties specified in

[44] Because the exemption from the clearing requirement in this provision requires the reporting of SB swaps pursuant to section 3C(e)(2) of the Exchange Act, 15 U.S.C. 78c–3(e)(2), market participants cannot comply with this provision until final rules have been adopted pursuant to such section 3C(e)(2).

[45] Because the mandatory clearing requirement is a predicate requirement for the end-user clearing exception set forth in section 3C(g) of the Exchange Act, 15 U.S.C. 78c–3(g), end users will not need to rely upon that exception until such time as an SB swap is determined by the Commission to be required to be cleared. Accordingly, the provisions of sections 3C(g)(1), (2) and (4) of the Exchange Act, 15 U.S.C. 78c–3(g)(1), (2) and (4), will not be triggered until that time.

[46] Since the mandatory clearing requirement is a predicate requirement for the end-user clearing exception set forth in section 3C(g) of the Exchange Act, 15 U.S.C. 78c–3(g), end users will not need to rely upon that exception until such time as a SB swap is determined by the Commission to be required to be cleared.

[47] Since the mandatory clearing requirement is a predicate requirement for any exemptions to it, this provision will not be trigged until such time as a SB swap is determined by the Commission to be required to be cleared.

[48] Section 3C(j) of the Exchange Act, 15 U.S.C. 78c–3(j), applies only to registered clearing agencies, including clearing agencies that provide clearance and settlement services for securities other than SB swaps. Accordingly, compliance with such requirements will be required on the later of the Effective Date and registration of the clearing agency. As noted above, three clearing agencies will be deemed registered on the Effective Date, in addition to clearing agencies already registered with the Commission. *See* discussion *infra* part II.H.

[49] 15 U.S.C. 78c–3(e)(1).

[50] 15 U.S.C. 78m–1.

[51] 15 U.S.C. 78c–3(e)(1).

[52] 15 U.S.C. 78mm.

[53] 15 U.S.C. 78c–3(e)(1).

[54] Similarly, we proposed—in rule 910 of Regulation SBSR—that no transaction reports for any SB swap executed on or after July 21, 2010 would have to be submitted to a registered SDR until six months after the date that an SDR registers with the Commission. *See* Regulation SBSR—Reporting and Dissemination of Security-Based Swap Information, *supra* note 9. As we stated in the Regulation SBSR proposing release, before reporting to a registered SDR could commence, persons with a duty to report would have to know the policies and procedures of the SDR and have time to implement necessary systems changes. *Id.*

[55] 15 U.S.C. 78c–3(g)(5)(B).

[56] *Id.*

[57] *Id.*

[58] *Id.*

[59] 15 U.S.C. 78c–3(b).

[60] 15 U.S.C. 78c–3(j)(1) and (2).

[61] 15 U.S.C. 78c–3(j)(1).

section 3C(j)(2) of the Exchange Act,[62] as well as, following rulemaking, the reporting provisions of section 3C(j)(3) of the Exchange Act.[63] The Commission finds that it is necessary or appropriate in the public interest, and consistent with the protection of investors to grant temporary exemptions from sections 3C(j)(1) and (2) of the Exchange Act[64] because there is potential uncertainty regarding the duties of a chief compliance officer as required by section 3C(j)(2).[65] Therefore, under this exemption, no person will be required to comply with section 3C(j)(1) or (2) of the Exchange Act[66] until the earliest compliance date set forth in any of the final rules regarding section 3C(j)(2) of the Exchange Act.[67]

With respect to the remaining provisions of section 3C of the Exchange Act, unless and until the Commission makes a determination that an SB swap is required to be cleared, section 3C of the Exchange Act, by its terms, does not require any SB swap to be cleared through a registered clearing agency or a clearing agency that is exempt from registration.[68] The Commission is required to adopt rules for clearing agencies' submissions to the Commission for review of SB swaps that clearing agencies seek to accept for clearing.[69] Thus, no SB swaps will be required to be submitted to the Commission for review until the compliance date set forth in such rules.

Request for Comment

- Are there other provisions of section 3C of the Exchange Act for which the Commission should grant temporary exemptive relief? Please specify which provisions and provide a detailed explanation of why granting such exemption would be necessary or appropriate in the public interest, and consistent with the protection of investors.

B. Security-Based Swap Execution Facilities

Section 3D of the Exchange Act, added by section 763(c) of the Dodd-Frank Act, contains the provisions regarding the registration of SB SEFs and the core principles with which registered SB SEFs must comply.[70] Table B below lists each provision of section 3D of the Exchange Act and identifies those with which compliance will be required on the Effective Date and those with which compliance will be triggered by registration of a person as a SB SEF, adoption of final rules, or other action by the Commission.[71] For the provisions with which compliance will be required on the Effective Date, Table B notes whether temporary relief from compliance is granted. The rationale and duration for such relief is explained in the text following the table. The table also includes provisions that authorize or direct the Commission to take specified action that, once undertaken, may impose compliance obligations upon market participants. Unless otherwise noted in the table below, these provisions do not require compliance by market participants on the Effective Date.

TABLE B—SECURITY-BASED SWAP EXECUTION FACILITIES—COMPLIANCE DATES

Exchange act section[72]	Compliance date		Authorizes/directs commission action[73]	Relief granted
	Upon effective date (July 16, 2011)	Upon registration, publication of final rules, or other commission action[74]		
3D(a)(1): Registration—in general		✓		Yes.[75]
3D(a)(2): Registration —dual registration		✓		N/A.
3D(b): Trading and trade processing		✓		N/A.
3D(c): Identification of facility used to trade SB swaps by national securities exchanges.	✓			Yes.
3D(d): Core principles for SB SEFs—compliance with core principles—in general and Commission rules and information requests.		✓		N/A.[76]
3D(e): Exemptions			✓	N/A.
3D(f): Rules			✓	N/A.

As indicated in Table B, the Commission finds, pursuant to section 36 of the Exchange Act,[77] that it is necessary or appropriate in the public interest, and is consistent with the protection of investors, to grant

[62] 15 U.S.C. 78c–3(j)(2).

[63] 15 U.S.C. 78c–3(j)(2).

[64] 15 U.S.C. 78c–3(j)(1) and (2).

[65] *See* Letter from DTCC (April 29, 2011) (stating that ''[w]hile DTCC fully supports the principle of a clearing agency designating a CCO, DTCC believes that some of the duties of the CCO specified in Proposed Rule 3Cj–1 require clarification in order to avoid an overly broad reading of those duties. DTCC believes that some of the duties of the CCO specified in the Proposed Rule go beyond those duties traditionally understood to be part of the compliance function.'').

[66] 15 U.S.C. 78c–3(j)(1) or (2).

[67] 15 U.S.C. 78c–3(j)(2).

[68] *See supra* note 45.

[69] *See* section 3C(b)(5) of the Exchange Act, 15 U.S.C. 78c–3(b)(5). The Commission published proposed rules regarding the submission process. *See* Process for Submissions for Review of Security-Based Swaps for Mandatory Clearing and Notice Filing Requirements for Clearing Agencies; Technical Amendments to Rule 19b–4 and Form 19b–4 Applicable to All Self-Regulatory Organizations, *supra* note 11.

[70] 15 U.S.C. 78c–4.

[71] *Id.*

[72] References to section 3D of the Exchange Act in this table are to 15 U.S.C. 78c–4.

[73] These provisions do not require compliance by market participants on the Effective Date, unless the relevant Commission action already has been undertaken. *See supra* note 26 and accompanying text.

[74] A number of Title VII provisions expressly (or implicitly) apply only to ''registered'' persons. Until the related registration processes for such persons have been established by final Commission rules, and such persons have become registered pursuant to such rules, they will not be required to comply with these Title VII provisions. If a Title VII provision requires a rulemaking, such provision will not necessarily go into effect on the Effective Date, but instead will go into effect ''not less than'' 60 days after publication of the related final rule or on July 16, 2011, whichever is later. *See* section 774 of the Dodd-Frank Act, 15 U.S.C. 77b note.

[75] Rulemaking is necessary to establish the form and manner of registration.

[76] Section 3D(d)(1) of the Exchange Act, 15 U.S.C. 78c–4(d)(1), states in part that ''[t]o be registered, and to maintain registration, as a security-based swap execution facility, the security-based swap execution facility shall comply with * * * any requirement that the Commission may impose by rule or regulation.'' Accordingly, compliance with such requirements will be required on the later of the registration of the SB SEF and the compliance date of any Commission rule establishing such requirements under section 3D of the Exchange Act, 15 U.S.C. 78c–4.

temporary exemptions from sections 3D(a)(1) and 3D(c) of the Exchange Act.[78] Section 3D(a)(1) of the Exchange Act states that no person may operate a facility for the trading or processing of SB swaps unless the facility is registered as a SB SEF or as a national securities exchange under section 3D of the Exchange Act.[79] The temporary exemption from section 3D(a)(1) would allow an entity that trades SB swaps and is not currently registered as a national securities exchange, or that cannot yet register as a SB SEF because final rules for such registration have not yet been adopted,[80] to continue trading SB swaps during this temporary period without registering as a national securities exchange or SB SEF.[81] The Commission finds that such action is necessary or appropriate in the public interest, and consistent with the protection of investors, to facilitate the operation of entities that trade SB swaps so that these instruments can continue to be traded without the need for entities that trade such instruments to register as national securities exchanges before the Commission has put in place a registration regime for SB SEFs, at which time the entities that operate these facilities would be able to choose between registration as a national securities exchange and a SB SEF.

Section 3D(c) of the Exchange Act requires that a national securities exchange (to the extent that it also operates an SB SEF and uses the same electronic trade execution system for listing and executing trades of SB swaps on or through the exchange and the facility) identify whether electronic trading of such SB swaps is taking place on or through the national securities exchange or the SB SEF.[82] The temporary exemption from section 3D(c) of the Exchange Act[83] would avoid legal uncertainty regarding whether a national securities exchange is operating as a SB SEF until further guidance is available.

The temporary exemptions from sections 3D(a)(1) and 3D(c) of the Exchange Act[84] will expire on the earliest compliance date set forth in any of the final rules regarding registration of SB SEFs.

Request for Comment

• Are there other provisions of section 3D of the Exchange Act for which the Commission should grant temporary exemptive relief? Please provide a detailed explanation of why granting such an exemption would be necessary or appropriate in the public interest, and consistent with the protection of investors.

C. Segregation of Collateral in Security-Based Swaps

Section 3E of the Exchange Act, added by section 763(d) of the Dodd-Frank Act, regulates the collection and handling of collateral that counterparties to SB swaps deliver to secure their obligations arising from such SB swaps and sets out certain rights of the counterparties who deliver such collateral.[85] Certain of these provisions require rulemaking by the Commission and thus will not require compliance on the Effective Date because the Commission will not have adopted a segregation rule by that date. Table C below lists each provision of section 3E of the Exchange Act and identifies those provisions that will require compliance on the Effective Date and those with which compliance will be triggered by the adoption of final rules or other action by the Commission.[86] For the provisions with which compliance will be required on the Effective Date, Table C notes whether temporary relief from compliance is granted. The rationale and duration for such relief is explained in the text following the table.

TABLE C—SEGREGATION OF COLLATERAL IN SECURITY-BASED SWAPS— COMPLIANCE DATES.

Exchange act section[87]	Compliance date		Authorizes/directs commission action[88]	Relief granted
	Upon effective date (July 16, 2011)	Upon registration, publication of final rules, or other commission action[89]		
3E(a): Registration requirement	✓			No.[90]
3E(b): Cleared SB swaps—segregation required; commingling prohibited	✓			No.[91]
3E(c)(1): Exceptions—use of funds	✓			N/A.
3E(c)(2): Exceptions—Commission action	✓			N/A.[92]
3E(d): Permitted investments	✓			N/A.
3E(d): Permitted investments—specified as permitted investments by the Commission.		✓		N/A.
3E(e): Prohibition	✓			No.[93]
3E(f): Segregation requirements for uncleared SB swaps	✓			Yes.
3E(g): Bankruptcy	✓			N/A.[94]

As indicated in Table C, the Commission is granting temporary

[77] 15 U.S.C. 78mm.

[78] 15 U.S.C. 78c–4(a)(1) and 78c–4(c).

[79] 15 U.S.C. 78c–4(a)(1).

[80] Such an entity could, for example, be an alternative trading system or a trading platform that is currently not registered with the Commission in any capacity. The Commission notes that, if such an entity were doing business as an alternative trading system, it would continue to be subject to the requirements of Regulation ATS (17 CFR 242.300 *et seq.*) during this temporary period.

[81] The Commission intends to separately consider temporary relief from the exchange registration requirements of Sections 5 and 6 of the Exchange Act, 15 U.S.C. 78f.

[82] 15 U.S.C. 78c–4(c).

[83] *Id.*

[84] 15 U.S.C. 78c–4(a)(1) and (c).

[85] 15 U.S.C. 78c–5.

[86] Section 3E of the Exchange Act, 15 U.S.C. 78c–5, contains no provisions that expressly apply only to registered SBSDs.

[87] References to section 3E of the Exchange Act in this table are to 15 U.S.C. 78c–5.

[88] These provisions do not require compliance by market participants on the Effective Date, unless the relevant Commission action already has been undertaken. *See supra* note 26 and accompanying text.

[89] A number of Title VII provisions expressly (or implicitly) apply only to ''registered'' persons. Until the related registration processes for such persons have been established by final Commission rules, and such persons have become registered pursuant

Continued

exemptions from compliance with section 3E(f) of the Exchange Act for SBS Entities.[95] Section 3E(f) of the Exchange Act requires SBS Entities to segregate initial margin amounts delivered by their counterparties in uncleared SB swap transactions if requested to do so by such counterparties.[96] Such segregation would require the establishment of accounts in which to segregate collateral with independent third-party custodians.[97] The establishment of these accounts and the adoption of policies and procedures setting forth the proper collection and maintenance of collateral will require expenditures of resources and time.[98]

The Commission finds that temporary exemption from section 3E(f) of the Exchange Act for SBS Entities is necessary or appropriate in the public interest, and is consistent with the protection of investors, because it would allow persons to register as an SBS Entity in accordance with the applicable registration requirements, once established, prior to expending resources to comply with the provisions of section 3E(f) of the Exchange Act as discussed above.[99] In addition, the Commission believes the exemption will give SBS Entities additional time to establish the necessary accounts and adopt the policies and procedures required by section 3E(f) of the Exchange Act.[100] Accordingly, the Commission is providing a temporary exemption pursuant to section 36 of the Exchange Act [101] from section 3E(f) of the Exchange Act [102] for SBS Entities. The temporary exemption will expire on the date upon which the rules adopted by the Commission to register SBSDs and MSBSPs become effective.

Section 3E(a) of the Exchange Act prohibits a person not registered as a broker, dealer, or SBSD from undertaking specified actions pertaining to the collection of margin associated with clearing an SB swap for an SB swap customer through a clearing agency.[103] Section 3E(a) of the Exchange Act requires that a person register with the Commission as a broker, dealer, or SBSD in order to comply with the provision.[104] Section 3E(b) of the Exchange Act obligates such persons to segregate initial margin amounts delivered by their counterparties in cleared SB swaps.[105] Sections 3E(c), (d), and (e) of the Exchange Act,[106] respectively, contain exceptions to section 3E(b) of the Exchange Act [107] permitting the commingling of funds for convenience in certain circumstances, prescribe certain obligations of the United States government in which margin collected may be invested, and contain other prohibitions on the use of margin.

The Commission is not granting exemptions from the requirements of sections 3E(a), (b), (c) or (e) of the Exchange Act.[108] Based on the Commission's experience in granting, and representations made by recipients of, previous exemptive orders for CCPs, the Commission understands that there are currently no CCPs offering customer clearing of SB swaps.[109] However, for CCPs that are planning to offer customer clearing of SB swaps before the compliance date for any of the final rules regarding registration of SBS Entities, the Commission will consider requests for relief from such CCPs on behalf of their participants from sections 3E(a), (b), and (e) of the Exchange Act, as appropriate, based on the applicable facts and circumstances.[110]

Request for Comment

- Under the stock-broker bankruptcy provisions of the Bankruptcy Code,[111] the description of which persons have the status as a customer of a broker-dealer with respect to their posted margin includes persons whose margin is required to be segregated. Given that reference to a segregation requirement, is any temporary exemption from section 3E(f) of the Exchange Act appropriate?
- Please explain the steps that must be taken for an SBSD to segregate initial margin for uncleared SB swap transactions. How long would it take to put in place such an arrangement with an independent third-party custodian? Would any existing documentation between the parties need to be amended?
- Are there other provisions of section 3E of the Exchange Act for which the Commission should consider granting a temporary exemption? Please specify the provision or provisions for which exemptions should be granted and provide a detailed explanation of why granting such exemptions would be necessary or appropriate in the public interest, and consistent with the protection of investors.

D. Security-Based Swap Antifraud Provisions

Section 9(j) of the Exchange Act,[112] added by 763(g) of the Dodd-Frank Act, includes a provision regarding the prevention of fraud, manipulation, and deception in connection with SB swaps. As indicated in Table D below, section 9(j) of the Exchange Act requires rulemaking.[113]

to such rules, they will not be required to comply with these Title VII provisions. If a Title VII provision requires a rulemaking, such provision will not necessarily go into effect on the Effective Date, but instead will go into effect ''not less than'' 60 days after publication of the related final rule or on July16, 2011, whichever is later. *See* section 774 of the Dodd-Frank Act, 15 U.S.C. 77b note.

[90] As explained below, the Commission will consider requests for relief from compliance with this provision by CCPs on behalf of participants.

[91] As explained below, the Commission will consider requests for relief from compliance with this provision by CCPs on behalf of participants.

[92] As explained below, the Commission will consider requests for relief from CCPs on behalf of participants.

[93] As explained below, the Commission will consider requests for relief from CCPs on behalf of participants.

[94] This section incorporates ''security-based swap'' into certain provisions of the Bankruptcy Code, 11 U.S.C. 1 *et seq.*

[95] 15 U.S.C. 78c–5(f).

[96] *Id.*

[97] 15 U.S.C. 78c–5(f)(1)(B) and (3).

[98] Notwithstanding the exemption granted, market participants in uncleared SB swaps may continue to voluntarily negotiate for and receive similar protections to those provided in section 3E(f) of the Exchange Act, 15 U.S.C. 78c–5(f), until compliance with such section 3E(f) is required.

[99] 15 U.S.C. 78c–5(f).

[100] *Id.*

[101] 15 U.S.C. 78mm.

[102] 15 U.S.C. 78c–5(f)(1), (f)(3), and (f)(4).

[103] 15 U.S.C. 78c–5(a).

[104] *Id.*

[105] 15 U.S.C. 78c–5(b).

[106] 15 U.S.C. 78c–5(c), (d), and (e).

[107] 15 U.S.C. 78c–5(b).

[108] 15 U.S.C. 78c–5(a), (b), (c) or (e).

[109] The Commission has granted temporary conditional exemptions to facilitate CDS clearing in connection with requests on behalf of ICE Clear Europe Limited; Eurex Clearing AG; Chicago Mercantile Exchange Inc.; ICE Trust US LLC; and LIFFE Administration and Management and LCH.Clearnet Ltd. *See infra* note 222 and accompanying text.

[110] 15 U.S.C. 78c–5(a), (b), and (e).

[111] *See generally* 11 U.S.C. 741 *et seq.*

[112] 15 U.S.C. 78i(j).

[113] *Id.* In the context of Section 774 of the Dodd-Frank Act, which addresses provisions that require rulemaking, we believe Section 9(j) requires rulemaking.

TABLE D—SECURITY-BASED SWAP ANTIFRAUD PROVISIONS—COMPLIANCE DATES

Exchange act section [114]	Compliance date		Authorizes/directs commission action [115]	Relief granted
	Upon effective date (July 16, 2011)	Upon registration, publication of final rules, or other commission action [116]		
9(j): Amends Exchange Act to make unlawful fraud, manipulation and deception in connection with SB swaps directs the Commission to engage in rulemaking to define and prescribe means reasonably designed to prevent, such fraud, manipulation and deception.	.....	✓	.....	N/A.

The Commission notes that, as of the Effective Date, SB swaps will be securities.[117] Thus, once the relevant provisions of the Dodd-Frank Act take effect,[118] persons effecting transactions in, or engaged in acts, practices, and courses of business involving, SB swaps will be subject to the Commission's rules and regulations that define and prescribe acts and practices involving securities that are manipulative, deceptive, fraudulent, or otherwise unlawful for purposes of the general antifraud and anti-manipulation provisions of the Federal securities laws, including sections 9(a) and 10(b) [119] of the Exchange Act, rule 10b–5 thereunder [120] (and the prohibitions against insider trading), section 15(c) of the Exchange Act,[121] and section 17(a) of the Securities Act,[122] among others.

E. Position Limits for Security-Based Swaps.

Section 10B of the Exchange Act, added by section 763(h) of the Dodd-Frank Act, provides that the Commission ''shall, by rule or regulation, as necessary or appropriate in the public interest or for the protection of investors'' establish limits on the size of positions in any SB swap that may be held by any person.[123] As indicated in Table E below, the provisions of section 10B authorize and direct the Commission to undertake certain actions pertaining to position limits.[124] These provisions will become effective on the Effective Date, but, by their plain language, pertain to Commission action. Accordingly, these provisions do not require compliance by market participants on the Effective Date.

TABLE E—POSITION LIMITS FOR SECURITY-BASED SWAPS—COMPLIANCE DATES

Exchange act section [125]	Compliance date		Authorizes/directs commission action [126]	Relief granted
	Upon effective date (July 16, 2011)	Upon registration, publication of final rules, or other commission action		
10B(a): Position limits	.....	.....	✓	N/A.
10B(b): Exemptions	.....	.....	✓	N/A.
10B(c): SRO rules	.....	.....	✓	N/A.
10B(d): Large trader reporting	.....	.....	✓	N/A.

F. Reporting of Security-Based Swaps

i. Public Availability of Security-Based Swap Data

Section 13(m) of the Exchange Act, added by section 763(i) of the Dodd-Frank Act, includes provisions regarding the reporting of SB swap transactions and the public dissemination of such reported information.[127] As set forth in Table F–1 below, certain of the statutory provisions of section 13(m) of the Exchange Act require Commission rulemaking or other action or are only applicable once there are registered SDRs to accept SB swap transaction data.[128] The table also includes provisions that authorize or direct the Commission to take specified action that, once undertaken, may impose compliance obligations upon market participants.[129] Unless otherwise noted in the table below, these provisions do not require compliance by market participants on the Effective Date. The remaining provisions of section 13(m) of the Exchange Act will require compliance on the Effective Date but do not impose any self-executing duties or

[114] References to section 9 of the Exchange Act in this table are to 15 U.S.C. 78i.

[115] These provisions do not require compliance by market participants on the Effective Date, unless the relevant Commission action already has been undertaken. *See supra* note 26 and accompanying text.

[116] A number of Title VII provisions expressly (or implicitly) apply only to ''registered'' persons. Until the related registration processes for such persons have been established by final Commission rules, and such persons have become registered pursuant to such rules, they will not be required to comply with these Title VII provisions. If a Title VII provision requires a rulemaking, such provision will not necessarily go into effect on the Effective Date, but instead will go into effect ''not less than'' 60 days after publication of the related final rule or on July 16, 2011, whichever is later. *See* section 774 of the Dodd-Frank Act, 15 U.S.C. 77b note.

[117] *See* discussion *infra.* Section 761(a)(2) of the Dodd-Frank Act amends the definition of ''security'' in section 3(a)(10) of the Exchange Act, 15 U.S.C. 78c(a)(10), to include SB swaps. Section 768(a)(1) of the Dodd-Frank Act amends the Securities Act to include SB swaps in the definition of ''security'' in section 2(a)(1) thereof, 15 U.S.C. 77b(a)(1).

[118] *See* section 774 of the Dodd-Frank Act.

[119] 15 U.S.C. 78i(a) and 78j(b).

[120] 17 CFR 240.10b–5.

[121] 15 U.S.C. 78o(c).

[122] 15 U.S.C. 77q(a).

[123] 15 U.S.C. 78j–2.

[124] *Id.*

[125] References to section 10B of the Exchange Act in this table are to 15 U.S.C. 78j–2.

[126] These provisions do not require compliance by market participants on the Effective Date, unless the relevant Commission action already has been undertaken. *See supra* note 26 and accompanying text.

[127] 15 U.S.C. 78m(m).

[128] *Id.*

[129] *See supra* note 26 and accompanying text.

requirements upon market participants.[130] Accordingly, the Commission is not granting temporary relief from compliance with any provisions of section 13(m) of the Exchange Act.

TABLE F—PUBLIC AVAILABILITY OF SECURITY-BASED SWAP DATA—COMPLIANCE DATES

Exchange Act Section [131]	Compliance Date		Authorizes/directs commission action [132]	Relief granted
	Upon effective date (July 16, 2011)	Upon registration, publication of final rules, or other commission action [133]		
13(m)(1)(A): In general—definition of real-time public reporting	✓			N/A.[134]
13(m)(1)(B): In general—purpose	✓			N/A.[135]
13(m)(1)(C): In general—general rule			✓	N/A.
13(m)(1)(D): In general—registered entities and public reporting			✓	N/A.
13(m)(1)(E): In general—rulemaking required			✓	N/A.
13(m)(1)(F): In general—timeliness of reporting		✓		N/A.
13(m)(1)(G): In general—reporting of swaps to registered SDRs		✓		N/A.
13(m)(1)(H): In general—registration of clearing agencies		✓		N/A.
13(m)(2): Semiannual and annual public reporting of aggregate SB swap data.			✓	N/A.

ii. Security-Based Swap Data Repositories.

Section 13(n) of the Exchange Act, added by section 763(i) of the Dodd-Frank Act, provides for the registration, operation, and governance of SDRs.[136] Certain of the statutory provisions in section 13(n) of the Exchange Act either require a rulemaking or other Commission action or apply only to SDRs once registered, rather than to SDRs generally.[137] Compliance with those provisions will not be required on the Effective Date because the Commission will not have adopted final rules (including rules regarding the manner and form of registration) by that date. The table also includes provisions that authorize or direct the Commission to take specified action that, once undertaken, may impose compliance obligations upon market participants.[138] Unless otherwise noted in the table below, these provisions do not require compliance by market participants on the Effective Date. Table F–2 below lists each provision of section 13(n) of the Exchange Act and identifies those provisions with which compliance will be required on the Effective Date and those with which compliance will be triggered by registration of a person as an SDR or by adoption of final rules by the Commission.[139] For the provisions with which compliance will be required on the Effective Date, Table F–2 notes whether temporary relief from compliance is granted. The rationale and duration for such relief is explained in the text following the table.

TABLE F–2—SECURITY-BASED SWAP DATA REPOSITORIES—COMPLIANCE DATES

Exchange act section[140]	Compliance date		Authorizes/directs commission action[141]	Relief granted
	Upon effective date (July 16, 2011)	Upon registration, publication of final rules, or other commission action[142]		
13(n)(1): Registration requirement		✓		N/A.[143]
13(n)(2): Inspection and examination		✓		N/A.
13(n)(3)(A): Compliance with core principles		✓		N/A.
13(n)(3)(B): Compliance with core principles—reasonable discretion of SDR		✓		N/A.
13(n)(4)(A): Standard setting—data identification			✓	N/A.
13(n)(4)(B): Standard setting—data collection and maintenance			✓	N/A.
13(n)(4)(C): Standard setting—comparability			✓	N/A.
13(n)(5)(A), (B),[144](C), (D)(ii), and (E): Duties		✓		N/A.
13(n)(5)(D)(i), (F), (G), and (H): Duties	✓			Yes.
13(n)(6)(A)—(B): Designation of chief compliance officer—in general; duties		✓		N/A.[145]
13(n)(6)(C): Designation of chief compliance officer—annual reports		✓		N/A.

[130] *Id.*

[131] References to section 13(m) of the Exchange Act in this table are to 15 U.S.C. 78m(m).

[132] These provisions do not require compliance by market participants on the Effective Date, unless the relevant Commission action already has been undertaken. *See supra* note 26 and accompanying text.

[133] A number of Title VII provisions expressly (or implicitly) apply only to ''registered'' persons. Until the related registration processes for such persons have been established by final Commission rules, and such persons have become registered pursuant to such rules, they will not be required to comply with these Title VII provisions. If a Title VII provision requires a rulemaking, such provision will not necessarily go into effect on the Effective Date, but instead will go into effect ''not less than'' 60 days after publication of the related final rule or on July 16, 2011, whichever is later. *See* section 774 of the Dodd-Frank Act, 15 U.S.C. 77b note.

[134] This section defines ''real-time public reporting'' for the purposes of section 13(m) of the Exchange Act, 15 U.S.C. 78m(m).

[135] This section sets forth the purpose of section 13(m) of the Exchange Act, 15 U.S.C. 78m(m).

[136] 15 U.S.C. 78m(n).

[137] *Id.*

[138] *See supra* note 26 and accompanying text.

[139] *Id.*

TABLE F–2—SECURITY-BASED SWAP DATA REPOSITORIES—COMPLIANCE DATES—Continued

Exchange act section[140]	Compliance date		Authorizes/directs commission action[141]	Relief granted
	Upon effective date (July 16, 2011)	Upon registration, publication of final rules, or other commission action[142]		
13(n)(7)(A): Core principles applicable to SDRs—market access to services and data.	✓			Yes.
13(n)(7)(B): Core principles applicable to SDRs—governance arrangements	✓			Yes.
13(n)(7)(C): Core principles applicable to SDRs—Conflicts of interest	✓			Yes.
13(n)(7)(D): Core principles applicable to SDRs—additional duties developed by Commission.			✓	N/A.
13(n)(8): Required registration for SDRs		✓		N/A.
13(n)(9): Rules			✓	N/A.

As indicated in Table F–2, the Commission finds, pursuant to section 36 of the Exchange Act,[146] that it is necessary or appropriate in the public interest, and is consistent with the protection of investors, to grant temporary exemptions from the provisions of sections 13(n)(5)(D)(i), 13(n)(5)(F), 13(n)(5)(G), 13(n)(5)(H), and 13(n)(7)(A) through (C) of the Exchange Act[147] that would otherwise impose obligations on SDRs as of the Effective Date. These temporary exemptions will allow SDRs additional time to develop the policies, procedures, and systems necessary to comply with the requirements of section 13(n) of the Exchange Act.[148]

The Commission finds that granting a temporary exemption from compliance with the requirements of section 13(n)(5)(D)(i) of the Exchange Act[149] is necessary or appropriate in the public interest, and is consistent with the protection of investors. Section 13(n)(5)(D)(i) of the Exchange Act requires an SDR to provide direct electronic access to the Commission or any designee of the Commission.[150] The Commission believes that this provision will require investment of significant time and resources by an SDR to implement the technology to be used to enable this direct electronic access and to coordinate with the Commission to establish its direct electronic access to data maintained by the SDR. The form and manner in which an SDR will provide direct electronic access may vary, depending in part on the amount of data stored at the SDR and how the SDR maintains that data. In addition, this requirement would obligate SDRs to make changes to existing systems and practices, or develop entirely new systems and practices, all of which would require significant investment of time and resources. The Commission believes it would be inefficient for an SDR to expend time and resources to develop the technological systems necessary to provide the direct electronic access required by section 13(n)(5)(D)(i) of the Exchange Act prior to knowing the capabilities the Commission rules will require these systems to have.[151]

Section 13(n)(5)(F) of the Exchange Act requires and SDR to maintain the privacy of any and all SB swap transaction information that the SDR receives from an SBSD, counterparty, or other registered entity.[152] The Commission finds that granting a temporary exemption from compliance with section 13(n)(5)(F) of the Exchange Act[153] is necessary or appropriate in the public interest because it will provide SDRs additional time to establish and implement robust policies and procedures to protect the privacy of data reported to them.

Section 13(n)(5)(G) of the Exchange Act requires that SDRs, on a confidential basis, and after notifying the Commission of the request, make available all data obtained by the SDR, including individual counterparty trade and position data, to certain enumerated entities.[154] Section 13(n)(5)(H) of the Exchange Act[155] requires that an SDR, before sharing information with any of the entities listed in section 13(n)(5)(G) of the Exchange Act,[156] (i) receive a written agreement from such entity that the entity will abide by certain confidentiality provisions relating to the information on SB swap transactions that is provided and (ii) each such entity shall agree to indemnify the SDR and the Commission for any expenses arising from litigation relating to the information provided. The Commission finds that granting a temporary exemption from compliance with the notification and indemnification requirements of sections 13(n)(5)(G) and 13(n)(5)(H) of the Exchange Act,[157] is necessary or appropriate in the public interest, and is consistent with the protection of investors, because it would enable relevant authorities to continue

[140] References to section 13(n) of the Exchange Act in this table are to 15 U.S.C. 78m(n).

[141] These provisions do not require compliance by market participants on the Effective Date, unless the relevant Commission action already has been undertaken. *See supra* note 26 and accompanying text.

[142] A number of Title VII provisions expressly (or implicitly) apply only to ''registered'' persons. Until the related registration processes for such persons have been established by final Commission rules, and such persons have become registered pursuant to such rules, they will not be required to comply with these Title VII provisions. If a Title VII provision requires a rulemaking, such provision will not necessarily go into effect on the Effective Date, but instead will go into effect ''not less than'' 60 days after publication of the related final rule or on July 16, 2011, whichever is later. *See* section 774 of the Dodd-Frank Act, 15 U.S.C. 77b note.

[143] In order to provide for orderly registration of SDRs, the Commission will need to propose rules regarding the form and manner of registration with the Commission as an SDR.

[144] The data for which an SDR needs to confirm the accuracy first needs to be prescribed by the Commission pursuant to section 13(n)(5)(A).

[145] Section 13(n)(6) of the Exchange Act, 15 U.S.C. 78m(n)(6), requires each SDR to designate a chief compliance officer who shall perform certain specified duties and prepare annual reports. Although the provision does not explicitly limit its application to registered SDRs, within the context of Title VII and section 13(n) of the Exchange Act, 15 U.S.C. 78m(n), which addresses registered SDRs, the Commission believes that Congress intended these requirements to apply only to SDRs that are registered or are required to register with the Commission.

[146] 15 U.S.C. 78mm.

[147] 15 U.S.C. 78m(n)(5)(D)(i), (n)(5)(F), (n)(5)(G), (n)(5)(H), and (n)(7)(A) through (C).

[148] 15 U.S.C. 78m(n).

[149] 15 U.S.C. 78m(n)(5)(D)(i).

[150] *Id.*

[151] *Id.*

[152] 15 U.S.C. 78m(n)(5)(G).

[153] *Id.*

[154] *Id.*

[155] 15 U.S.C. 78m(n)(5)(G).

[156] 15 U.S.C. 78m(n)(5)(H).

[157] 15 U.S.C. 78m(n)(5)(G) and 78m(n)(5)(H).

to have access to data maintained by SDRs necessary to fulfill their respective mandates while the Commission considers various issues related to these requirements.

The Commission also finds that it is necessary or appropriate in the public interest, and is consistent with the protection of investors, to grant temporary exemptions from section 13(n)(7)(B) of the Exchange Act's [158] requirement that SDRs establish transparent governance arrangements for certain enumerated reasons. Delaying compliance with this requirement until the Commission's final rules setting forth the full panoply of duties applicable to SDRs have been adopted would avoid possible complications and unnecessary expenditures of time and resources by an SDR. It also would avoid unnecessary disruption of an SDR's governance structure, which could adversely impact the SDR's operations and could result in unnecessary expenditures of time and resources by the SDR. In addition, the Commission finds that it is necessary or appropriate in the public interest, and is consistent with the protection of investors, to grant temporary relief from compliance with (i) section 13(n)(7)(A) of the Exchange Act,[159] which prohibits an SDR from adopting any rule or taking any action that results in any unreasonable restraint of trade or impose any material anticompetitive burden on the trading, clearing, or reporting of transactions and (ii) section 13(n)(7)(C) of the Exchange Act,[160] which requires that SDRs establish rules to minimize conflicts of interest and establish a process for resolving conflicts of interest. The Commission believes that, until SDRs can register with the Commission, they should be given additional time to establish and implement the policies and procedures required by these provisions. In addition, providing additional time through a temporary exemption for SDRs to examine current business practices and any past issues they may have dealt with will likely result in more robust policies and procedures that will better protect market participants.

The temporary exemption granted by the Commission from compliance with the requirements of sections 13(n)(5)(D)(i), 13(n)(5)(F), 13(n)(5)(G), 13(n)(5)(H), 13(n)(7)(A), 13(n)(7)(B), and 13(n)(7)(C) of the Exchange Act [161] will expire on the earlier of (1) the date the Commission grants registration to the SDR and (2) the earliest compliance date set forth in any of the final rules regarding the registration of SDRs.

Request for Comment:

• Are there other provisions in addition to those identified above for which compliance is required as of the Effective Date but exemptive relief is or is not appropriate? If so, please specify those provisions and provide a detailed explanation of why granting such an exemption is or is not necessary or appropriate in the public interest, or consistent with the protection of investors.

iii. Reporting and Recordkeeping for Security-Based Swaps

Section 13A of the Exchange Act, added by section 766(a) of the Dodd-Frank Act, generally sets forth reporting requirements for SB swaps that are not cleared.[162] As set forth in Table F–3 below, certain of the statutory provisions of section 13A of the Exchange Act require Commission rulemaking or other action or are only applicable if a registered SDR will accept reports.[163] The table also includes provisions that authorize or direct the Commission to take specified action that, once undertaken, may impose compliance obligations upon market participants.[164] Unless otherwise noted in the table below, these provisions do not require compliance by market participants on the Effective Date. The remaining provisions of section 13A of the Exchange Act will become effective on the Effective Date but do not impose any duties or requirements upon market participants.[165] Accordingly, the Commission is not granting temporary relief from compliance with any provisions of section 13A of the Exchange Act.[166]

TABLE F–3—REPORTING AND RECORDKEEPING FOR SECURITY-BASED SWAPS—COMPLIANCE DATES

Exchange act section [167]	Compliance Date		Authorizes/directs commission action [168]	Relief granted
	Upon effective date (July 16, 2011)	Upon registration, publication of final rules, or other commission action [169]		
13A(a)(1)(A): Required reporting of SB swaps not accepted by a clearing agency or derivatives clearing organization—in general—reporting to SDRs.		✓		N/A.[170]
13A(a)(1)(B): Required reporting of SB swaps not accepted by a clearing agency or derivatives clearing organization—in general—reporting to the Commission.		✓		N/A.[171]
13A(a)(2)(A): Required reporting of SB swaps not accepted by a clearing agency or derivatives clearing organization—transition rule pre-enactment SB swaps.		✓		N/A.[172]
13A(a)(2)(B): Required reporting of SB swaps not accepted by a clearing agency or derivatives clearing organization—rulemaking for transition rule pre-enactment SB swaps.			✓	N/A.
13A(a)(2)(C): Required reporting of SB swaps not accepted by a clearing agency or derivatives clearing organization—effective date.	✓			N/A.[173]
13A(a)(3): Reporting obligations [174]		✓		N/A.
13A(b): Duties of certain individuals		✓		N/A.[175]

[158] 15 U.S.C. 78m(n)(7)(B).

[159] 15 U.S.C. 78m(n)(7)(A).

[160] 15 U.S.C. 78m(n)(7)(C).

[161] 15 U.S.C. 78m(n)(5)(D)(i), (n)(5)(G), (n)(5)(H)(ii), (n)(7)(A), (n)(7)(B), and (n)(7)(C).

[162] 15 U.S.C. 78m–1.

[163] *Id.*

[164] *See supra* note 26 and accompanying text.

[165] *Id.*

[166] *Id.*

TABLE F–3—REPORTING AND RECORDKEEPING FOR SECURITY-BASED SWAPS—COMPLIANCE DATES—Continued

Exchange act section [167]	Compliance Date		Authorizes/directs commission action [168]	Relief granted
	Upon effective date (July 16, 2011)	Upon registration, publication of final rules, or other commission action [169]		
13A(c)(1): Requirements—provision of reports on SB swaps to the Commission.		✓		N/A.
13A(c)(2): Requirements—recordkeeping requirement		✓		N/A.
13A(d): Identical data			✓	N/A.

Request for Comment

• Are there provisions of section 13A of the Exchange Act for which the Commission should grant temporary exemptive relief? Please specify which provisions and provide a detailed explanation of why granting such exemption would be necessary or appropriate in the public interest, and consistent with the protection of investors.

G. Registration and Regulation of Security-Based Swap Dealers and Major Security-Based Swap Participants

Section 15F of the Exchange Act, added by section 764(a) of the Dodd-Frank Act, establishes requirements for registration and comprehensive oversight of SBS Entities.[176] Many of the provisions of section 15F of the Exchange Act either require rulemaking or other action by the Commission [177] or apply only to SBS Entities once registered, rather than to SBS Entities generally.[178] Those provisions that either require rulemaking or other action by the Commission or apply only to registered SBS Entities will not require compliance on the Effective Date because the Commission will not have adopted final rules (including rules regarding the manner and form of registration) or taken other required action by that date. Table G below lists each provision of section 15F of the Exchange Act [179] and identifies those provisions with which compliance will be required on the Effective Date and those with which compliance will be triggered by registration of SBS Entities or by the adoption of final rules or other action by the Commission. The table also includes provisions that authorize or direct the Commission to take specified action that, once undertaken, may impose compliance obligations upon market participants.[180] Unless otherwise noted in the table below, these provisions do not require compliance by market participants on the Effective Date. For the provisions with which compliance will be required on the Effective Date, Table G notes whether the Commission is providing temporary relief from compliance. The rationale and duration for such relief is explained in the text following the table.

[167] References to section 13A of the Exchange Act in this table are to 15 U.S.C. 78m–1.

[168] These provisions do not require compliance by market participants on the Effective Date, unless the relevant Commission action already has been undertaken. *See supra* note 26 and accompanying text.

[169] A number of Title VII provisions expressly (or implicitly) apply only to ''registered'' persons. Until the related registration processes for such persons have been established by final Commission rules, and such persons have become registered pursuant to such rules, they will not be required to comply with these Title VII provisions. If a Title VII provision requires a rulemaking, such provision will not necessarily go into effect on the Effective Date, but instead will go into effect ''not less than'' 60 days after publication of the related final rule or on July 16, 2011, whichever is later. *See* section 774 of the Dodd-Frank Act, 15 U.S.C. 77b note.

[170] Section 13A(a)(1) of the Exchange Act, 15 U.S.C. 78m–1(a)(1), states in part that ''[e]ach security-based swap that is not accepted for clearing by any clearing agency or derivatives clearing organization shall be reported to (A) a security-based swap data repository described in section 13(n) [of the Exchange Act, 15 U.S.C. 78m(n)].'' Because the SDRs described in section 13(n) of the Exchange Act, 15 U.S.C. 78m(n), are required by section 13(n)(1) of the Exchange Act, 15 U.S.C. 78m(n)(1), to be registered, the Commission believes this requirement is not triggered until an SDR is registered.

[171] Section 13A(a)(1)(B) of the Exchange Act, 15 U.S.C. 78m–1(a)(1)(B), provides for an alternative method of reporting if there is no SDR that will accept a report; however, the time frame for that reporting requirement must be established by Commission rule.

[172] Section 13A(a)(2) of the Exchange Act, 15 U.S.C. 78m–1(a)(2), required the Commission to promulgate an interim final rule regarding reporting of pre-enactment SB swaps and states in part that each such pre-enactment SB swap, the terms of which have not expired as of such date, ''shall be reported to a registered security-based swap data repository or the Commission by a date that is not later than (i) 30 days after issuance of the interim final rule; or (ii) such other period as the Commission determines to be appropriate.'' The effective date of the interim final rule was October 20, 2010. However, pursuant to the interim final temporary rule issued by the Commission on reporting of pre-enactment SB swap data, specified counterparties to such pre-enactment SB swaps are required to (1) report certain information to a registered SDR or the Commission by the compliance date established in the reporting rules required under sections 3C(e) and 13A(a)(1) of the Exchange Act, 15 U.S.C. 78c–3(e) and 78m–1(a)(1), or within 60 days after a registered SDR commences operations to receive and maintain data concerning such SB swap, whichever occurs first, and (2) report to the Commission any information relating to such pre-enactment SB swaps upon request of the Commission. No SDR is registered yet to accept SB swap data and the reporting rules under section 3C(e) have not yet been adopted. In addition, the Commission stated, in an interpretative note to the interim final rule, its belief that it is necessary for a counterparty, that may be required to report transactions under the interim final rule, to retain all information relating to the terms of pre-enactment security-based swaps in order for that counterparty to be able to comply with the reporting requirements of the interim final rule. *See* Reporting of Security-Based Swap Transaction Data, 75 FR 64643 (Oct. 20, 2010). The reporting rules under sections 3C(e) and 13A(a)(1) of the Exchange Act, 15 U.S.C. 78c–3(e) and 78m–1(a)(1), are included in a separate release. *See* Regulation SBSR—Reporting and Dissemination of Security-Based Swap Information, *supra* note 9.

[173] This section provides that the effective date of section 13A of the Exchange Act, 15 U.S.C. 78m–1, is the date of enactment of section 13A of the Exchange Act, 15 U.S.C. 78m–1. However, compliance will not be required until applicable rules and regulations regarding registered SDRs are in place.

[174] *See supra* note 170.

[175] This section defines the individuals and entities to which the requirements of section 13A(c) of the Exchange Act, 15 U.S.C. 78m–1(c), apply.

[176] 15 U.S.C. 78o–10.

[177] *See, e.g.,* section 15F(b)(2) of the Exchange Act, 15 U.S.C. 78o–10(b)(2) (providing that the registration application of SBS Entities ''shall be made in such form and manner as prescribed by the Commission'').

[178] *See, e.g.,* section 15F(h)(1) of the Exchange Act, 15 U.S.C. 78o–10(h)(1) (providing that registered SBS Entities shall conform to certain prescribed business conduct standards); section 15F(h)(6) of the Exchange Act, 15 U.S.C. 78o–10(h)(6) (directing the Commission to prescribe rules to implement the business conduct requirements of subsection (h) of such section 15F applicable to registered SBS Entities).

[179] 15 U.S.C. 78o–10.

[180] *See supra* note 26 and accompanying text.

TABLE G—REGISTRATION AND REGULATION OF SECURITY-BASED SWAP DEALERS AND MAJOR SECURITY-BASED SWAP PARTICIPANTS—COMPLIANCE DATES

Exchange act section [181]	Compliance date		Authorizes/directs/limits commission action [182]	Relief granted
	Upon effective date (July 16, 2011)	Upon registration, publication of final rules, or other commission action [183]		
15F(a): Registration of SBSDs and MSBSPs		✓		N/A.[184]
15F(b)(1)–(3): Requirements—in general; contents; expiration		✓		N/A.
15F(b)(4): Requirements—rules			✓	N/A.
15F(b)(5): Requirements—transition			✓	N/A.
15F(b)(6): Requirements—statutory disqualification	✓			Yes
15F(c): Dual registration—SBS Entities		✓		N/A.
15F(d): Rulemaking			✓	N/A.
15F(e)(1): Capital and margin requirements—in general		✓		N/A.[185]
15F(e)(2): Capital and margin requirements—rules			✓	N/A.[186]
15F(e)(3)(A): Capital and margin requirements			✓	N/A.
15F(e)(3)(B)(i): Capital and margin requirements—rule of construction; in general.			✓[187]	N/A.
15F(e)(3)(B)(ii): Capital and margin requirements—rule of construction; futures commission merchants and other dealers.	✓			N/A.[188]
15F(e)(3)(C), (D): Capital and margin requirements—rule of construction; margin requirements and; comparability.			✓	N/A.[189]
15F(f)(1): Reporting and recordkeeping—in general		✓		N/A.[190]
15F(f)(2): Reporting and recordkeeping—rules			✓	N/A.
15F(g)(1)–(4): Daily trading records—in general; information requirements; counterparty records; audit trail.		✓		N/A.[191]
15F(g)(5): Daily trading records—rules			✓	N/A.
15F(h)(1): Business conduct standards		✓		N/A.[192]
15F(h)(2): Business conduct standards—responsibilities with respect to special entities.		✓		N/A.[193]
15F(h)(3): Business conduct standards—business conduct requirements.			✓	N/A.[194]
15F(h)(4): Business conduct standards—special requirements for SBSDs acting as advisors.		✓		N/A.[195]
15F(h)(5)(A): Business conduct standards—special requirements for SBSDs as counterparties to special entities.		✓		N/A.[196]
15F(h)(5)(B): Business conduct standards—Commission authority.			✓	N/A.
15F(h)(6): Business conduct standards—rules			✓	N/A.
15F(h)(7): Business conduct standards—applicability	✓			N/A.[197]
15F(i)(1): Documentation standards—in general		✓		N/A.[198]
15F(i)(2): Documentation standards—rules			✓	N/A.
15F(j)(1)–(6): Duties—monitoring of trading; risk management procedures; disclosure of general information; ability to obtain information; conflicts of interest; antitrust considerations.		✓		N/A.
15F(j)(7): Duties—rules			✓	N/A.
15F(k)(1)–(2): Designation of chief compliance officer—in general; duties.		✓		N/A.[199]
15F(k)(3): Designation of chief compliance officer—annual reports.		✓		N/A.
15F(l): Enforcement and administrative proceeding authority.[200]			✓[201]	N/A.

[181] References to section 15F of the Exchange Act in this table are to 15 U.S.C. 78o–10.

[182] These provisions do not require compliance by market participants on the Effective Date, unless the relevant Commission action already has been undertaken. *See supra* note 26 and accompanying text.

[183] A number of Title VII provisions expressly (or implicitly) apply only to ''registered'' persons. Until the related registration processes for such persons have been established by final Commission rules, and such persons have become registered pursuant to such rules, they will not be required to comply with these Title VII provisions. If a Title VII provision requires a rulemaking, such provision will not necessarily go into effect on the Effective Date, but instead will go into effect ''not less than'' 60 days after publication of the related final rule or on July16, 2011, whichever is later. *See* section 774 of the Dodd-Frank Act, 15 U.S.C. 77b note.

[184] Section 15F(b)(2)(A) of the Exchange Act, 15 U.S.C. 78o–10(b)(2)(A), requires SBS Entities to register as such ''in such form and manner as prescribed by the Commission * * *''

[185] Section 15F(e)(1) of the Exchange Act, 15 U.S.C. 78o–10(e)(1), states in part that registered SBS Entities for which there is not a prudential regulator ''shall meet such minimum capital requirements and minimum initial and variation and margin requirements as the Commission shall by rule or regulation prescribe * * *'' Accordingly, compliance with such requirements will be required on the later of the registration of a person as an SBS Entity and the compliance date of any Commission rule establishing these capital and margin requirements.

[186] For SBS Entities for which there is a prudential regulator, the prudential regulator shall consult with the Commission and the CFTC in establishing capital and margin requirements.

[187] Section 15F(e)(3)(B)(i) of the Exchange Act, 15 U.S.C. 78o–10(e)(3)(B)(i), provides that nothing in section 15F of the Exchange Act, 15 U.S.C. 78o–10, shall limit the authority of the Commission or the CFTC to set financial responsibility rules for SBS Entities over which they have jurisdiction, respectively.

[188] Section 15F(e)(3)(B)(ii) of the Exchange Act, 15 U.S.C. 78o–10(e)(3)(B)(ii), provides that a futures commission merchant, introducing broker, broker,

or dealer shall maintain sufficient capital to comply with the stricter of any applicable capital requirements to which such futures commission merchant, introducing broker, broker, or dealer is subject to under section 15(f) of the Exchange Act, 15 U.S.C. 78o–10(f), or the Commodity Exchange Act.

[189] Section 15F(e)(3)(C) of the Exchange Act, 15 U.S.C. 78o–10(e)(3)(C), provides, *inter alia,* that prudential regulators, the Commission, and the CFTC shall consult and ''to the maximum extent practicable'' establish and maintain comparable minimum capital and margin requirements.

[190] Section 15F(f)(1) of the Exchange Act, 15 U.S.C. 78o–10(f)(1), states in part that registered SBS Entities ''shall make such reports as are required by the Commission, by rule or regulation, regarding the transactions and positions and financial condition of the registered security-based swap dealer or major security-based swap participant'' and ''shall keep books and records * * * in such form and manner and for such period as may be prescribed by the Commission by rule or regulation * * *'' Accordingly, compliance with such reporting and recordkeeping requirements will be required on the later of the registration of a person as an SBS Entity and the compliance date of any Commission rule establishing these reporting and recordkeeping requirements.

[191] Section 15F(g)(1) of the Exchange Act, 15 U.S.C. 78o–10(g)(1), states in part that each registered SBS Entity shall maintain daily trading records and recorded communications ''for such period as may be required by the Commission by rule or regulation.'' In addition, section 15F(g)(2) of the Exchange Act, 15 U.S.C. 78o–10(g)(2) provides that the daily trading records shall include ''such information as the Commission shall require by rule or regulation.'' Accordingly, compliance with such recordkeeping requirements will be required on the later of the registration of a person as an SBS Entity and the compliance date of the Commission rule establishing these recordkeeping requirements.

[192] Section 15F(h)(6) of the Exchange Act, 15 U.S.C. 78o–10(h)(6), directs the Commission to ''prescribe rules under this subsection [(h) of the Exchange Act, 15 U.S.C. 78o–10(h),] governing business conduct standards.'' Accordingly, business conduct standards pursuant to section 15F(h) of the Exchange Act, 15 U.S.C. 78o–10(h), will be established by rule and compliance will be required on the compliance date of the Commission rule establishing these business conduct standards. *See also infra* note 195.

[193] *Id.*

[194] *Id.*

[195] *Id.* The Commission notes, however, that, as of the Effective Date, SB swaps will be securities and will be subject to the Commission's authority under sections 9(a) and 10(b) of the Exchange Act, 15 U.S.C. 78i(a) and 78j(b), including rule 10b–5 thereunder, 17 CFR 240.10b–5, section 15(c) of the Exchange Act, 15 U.S.C. 78o(c), and section 17(a) of the Securities Act, 15 U.S.C. 77q(a), among others. *See* discussion *supra* note 117 and accompanying text.

[196] *See supra* note 192.

[197] This section limits the applicability of section 15F(h) of the Exchange Act, 15 U.S.C. 78o–10(h).

[198] Section 15F(i) of the Exchange Act, 15 U.S.C. 78o–10(i), states in part that each registered SBS Entity ''shall conform with such standards as may be prescribed by the Commission, by rule or regulation, that relate to timely and accurate confirmation, processing, netting, documentation, and valuation of all security-based swaps.'' Accordingly, compliance with such requirements will be required on the later of the registration of a person as an SBS Entity and the compliance date of the Commission rule establishing these documentation standards.

[199] Section 15F(k) of the Exchange Act, 15 U.S.C. 78o–10(k), requires each SBS Entity to designate a chief compliance officer who shall perform certain specified duties and prepare annual reports. Although the provision does not explicitly limit its application to a registered SBS Entity, within the context of Title VII and section 15F of the Exchange Act, 15 U.S.C. 78o–10, which regulates registered SBS Entities, the Commission believes that Congress intended these requirements to apply only to SBS Entities that are registered or are required to register with the Commission.

[200] As discussed above, provisions in this column that require Commission action will be effective on the Effective Date. In particular, if (after the Effective Date) the Commission has issued an order pursuant to section 15F(l)(3) of the Exchange Act, 15 U.S.C. 78o–10(l)(3), then, section 15F(l)(4) of the Exchange Act, 15 U.S.C. 78o–10(l)(4), will be applicable and will require Commission consent for persons subject to such an order to be associated with a SBS Entity.

[201] In addition to Commission authority, section 15F(l) of the Exchange Act, 15 U.S.C. 78o–10(l), also provides enforcement authority to prudential regulators for SBS Entities for which they are the prudential regulator.

[202] 15 U.S.C. 78o–10(b)(6).

[203] 15 U.S.C. 78c(a)(39).

[204] 15 U.S.C. 78o–10(b)(6).

[205] *Id.*

[206] When such a person seeks admission to or continuance in membership or association, the Commission and the SRO have the opportunity to give special review to such person and to restrict or prevent entry into, or continuance in, the business where appropriate in the public interest and for the protection of investors. *See* Senate Comm. on Banking, Housing, and Urban Affairs, The Securities Act Amendments of 1989, S. Rep. No. 101–105, at 39 (1989); Provision for Notices by Self-Regulatory Organizations of Stays of Such Actions; Appeals; and Admissions to Membership or Association of Disqualified Persons, 42 FR 36409 (Jul. 14, 1977) (adopting rule 19h–1 under the Exchange Act, 17 CFR 240.19h–1, and providing rules for process of filing notices, content of notices, and Commission determination).

[207] 17 CFR 201.193.

[208] 15 U.S.C. 78o–10(b)(6).

[209] *Id.*

[210] 15 U.S.C. 78c(a)(39).

As indicated in Table G, the Commission is providing a temporary exception for SBS Entities from compliance with section 15F(b)(6) of the Exchange Act.[202] Section 15F(b)(6) of the Exchange Act prohibits an SBS Entity from permitting an associated person who is subject to a statutory disqualification, as defined in section 3(a)(39) of the Exchange Act,[203] to effect or be involved in effecting SB swaps on its behalf if the SBS Entity knew or should have known of the statutory disqualification.[204] Section 15F(b)(6) expressly authorizes the Commission to establish exceptions to this provision by rule, regulation, or order.[205] This authority is similar to authority provided to the Commission with respect to the ''traditional'' securities industry, *i.e.,* the industry regulated under the Exchange Act prior to the Dodd-Frank Act amendments. This existing Exchange Act authority permits self-regulatory organizations (''SROs''), subject to Commission review, to allow, among other things, a person subject to a statutory disqualification to associate with a broker-dealer.[206]

Similarly, Commission rule 193 (Applications by Barred Individuals for Consent to Associate) provides a process by which persons that are not regulated by a SRO (*e.g.,* an investment adviser, an investment company, or a transfer agent) can seek to reenter the securities industry despite previously being barred by the Commission.[207]

The Commission intends to separately consider issues relating to how an associated person of an SBS Entity subject to a statutory disqualification may be involved in the SB swap business of the SBS Entity. The Commission believes that existing business relationships and market activity may be unnecessarily disrupted if market participants were required to comply with section 15F(b)(6) of the Exchange Act[208] before the Commission considered, through notice and comment rulemaking, whether to adopt a procedure for potential modifications of the effect of statutory disqualifications under Title VII for SBS Entities and what any such procedure would require. The Commission, therefore, by this Order and pursuant to the authority granted in section 15F(b)(6) of the Exchange Act, is providing a temporary and limited exception for SBS Entities from the application of the prohibition in section 15F(b)(6) of the Exchange Act.[209] Specifically, persons subject to a statutory disqualification (as defined in section 3(a)(39) of the Exchange Act[210]) who are, as of the Effective Date, currently associated with an SBS Entity and who effect or are involved in effecting SB swaps on behalf of such SBS Entity may continue to be associated with any SBS Entity until the date upon which rules adopted by the Commission to register SBS Entities become effective.

Request for Comment:

- Are there certain persons subject to statutory disqualification who should not be permitted to remain associated with an SBS Entity during the time period of the exception, for example, based upon the nature of the underlying conduct or sanction that resulted in the disqualification?
- Should there be any differentiation in relief from section 15F(b)(6) of the Exchange Act based upon the nature of the person, *e.g.,* a natural person or an entity? If so, how and why?
- Are there persons who are not currently associated with an SBS Entity but who should be able to associate with

such entities notwithstanding their statutory disqualification until such time as a procedural rule defining the application of section 15F(b)(6) of the Exchange Act is in place?

H. Registration of Clearing Agencies for Security-Based Swaps

Section 17A of the Exchange Act, amended by section 763(b) of the Dodd-Frank Act,[211] requires registration of persons performing the functions of a clearing agency with respect to SB swaps. Many of the provisions of section 17A of the Exchange Act either require rulemaking or other action by the Commission or apply only to clearing agencies once registered. Those provisions that either require rulemaking or other action by the Commission or apply only to registered clearing agencies will not require compliance on the Effective Date. Table H below lists each provision of section 17A of the Exchange Act[212] that was added by the Dodd-Frank Act and identifies those provisions with which compliance will be required on the Effective Date and those with which compliance will be triggered by registration of clearing agencies or by the adoption of final rules or other action by the Commission. The table also includes provisions that authorize or direct the Commission to take specified action that, once undertaken, may impose compliance obligations upon market participants.[213] Unless otherwise noted in the table below, these provisions do not require compliance by market participants on the Effective Date. For the provisions with which compliance will be required on the Effective Date, Table H notes whether temporary relief from compliance is granted.

TABLE H—REGISTRATION OF CLEARING AGENCIES FOR SECURITY-BASED SWAPS—COMPLIANCE DATES

Exchange Act Section[214]	Compliance Date		Authorizes/directs commission action[215]	Relief granted
	Upon effective date (July 16, 2011)	Upon registration, publication of final rules, or other commission action[216]		
17A(g): Registration requirement		✓		N/A[217]
17A(h): Voluntary registration	✓			No.[218]
17A(i): Standards for clearing agencies clearing SB swap transactions		✓		N/A.[219]
17A(j): Rules			✓	N/A.
17A(k): Exceptions			✓	N/A.
17A(l)(1)–(2): Existing depository institutions and derivative clearing organizations—in general; conversion of depository institutions.	✓			No.[220]
17A(l)(3): Existing depository institutions and derivative clearing organizations—sharing of information.			✓	N/A.[221]
17A(m): Modification of core principles			✓	N/A.

As of July 16, 2011, ICE Trust U.S. LLC, ICE Clear Europe Limited and the Chicago Mercantile Exchange Inc., which are operating pursuant to exemptive authority granted by the Commission to clear CDS,[222] will be

[211] 15 U.S.C. 78q–1.

[212] *Id.*

[213] *See supra* note 26 and accompanying text.

[214] References to section 17A of the Exchange Act in this table are to 15 U.S.C. 78q–1.

[215] These provisions do not require compliance by market participants on the Effective Date, unless the relevant Commission action already has been undertaken. *See supra* note 26 and accompanying text.

[216] A number of Title VII provisions expressly (or implicitly) apply only to ''registered'' persons. Until the related registration processes for such persons have been established by final Commission rules, and such persons have become registered pursuant to such rules, they will not be required to comply with these Title VII provisions. If a Title VII provision requires a rulemaking, such provision will not necessarily go into effect on the Effective Date, but instead will go into effect ''not less than'' 60 days after publication of the related final rule or on July16, 2011, whichever is later. *See* section 774 of the Dodd-Frank Act, 15 U.S.C. 77b note.

[217] Section 17A(g) of the Exchange Act, 15 U.S.C. 78q–1(g), will not require compliance as of the Effective Date because sections 17A(i) and (j) of the Exchange Act, 15 U.S.C. 78q–1(i) and (j), require rulemaking regarding registration of clearing agencies that clear SB swap transactions. The Commission notes that the general clearing agency registration requirement under section 17A(b) of the Exchange Act, 15 U.S.C. 78q–1(b), also will apply to SB swap clearing agencies when the provisions amending the definitions of ''security'' to include SB swaps become effective on the Effective Date. *See supra* note 17. As noted above, however, the Commission intends to provide temporary relief from certain provisions of the Exchange Act that would otherwise be applicable to SB swaps. *See supra* note 22 and accompanying text. This includes temporary relief from the clearing agency registration requirement to certain persons with respect to SB swaps. Specifically, persons that currently provide important post-trade, non-CCP clearance and settlement processing services for SB swaps may be required to register as a clearing agency as of the Effective Date (including trade matching, collateral management, and tear-up/compression services). Temporary relief for such persons would provide time for the Commission to consider comments from industry on the issue of registration of these non-CCP clearance and settlement service providers, and to consider possible alternatives to full registration as clearing agencies. *See infra* note 223 and accompanying text.

[218] Section 17A(h) provides that a person that clears trades that are not required to be cleared may nevertheless register as a clearing agency with the Commission. It is a voluntary provision.

[219] Rules adopted under section 17A(i) of the Exchange Act, 15 U.S.C. 78q–1(i), apply only to registered clearing agencies. Accordingly, compliance with such requirements will be required on the later of the registration of the clearing agency and the compliance date of the Commission rule establishing these clearing agency standards.

[220] Section 17A(l)(1)–(2) provides for the deemed registration of certain clearing agencies. *See infra* note 223.

[221] Section 17A(l)(3) of the Exchange Act, 15 U.S.C. 78q–l(3), provides that the CFTC shall share certain information with the Commission regarding derivatives clearing organizations deemed to be registered.

[222] The Commission has authorized five entities to clear credit default swaps. *See* Exchange Act Release Nos. 60372 (July 23, 2009), 74 FR 37748 (July 29, 2009), 61973 (Apr. 23, 2010), 75 FR 22656 (Apr. 29, 2010) and 63389 (Nov. 29, 2010), 75 FR 75520 (Dec. 3, 2010) (CDS clearing by ICE Clear Europe Limited); 60373 (July 23, 2009), 74 FR 37740 (July 29, 2009), 61975 (Apr. 23, 2010), 75 FR 22641 (Apr. 29, 2010) and 63390 (Nov. 29, 2010), 75 FR 75518 (Dec. 3, 2010), (CDS clearing by Eurex Clearing AG); 59578 (Mar. 13, 2009), 74 FR 11781 (Mar. 19, 2009), 61164 (Dec. 14, 2009), 74 FR 67258 (Dec. 18, 2009), 61803 (Mar. 30, 2010), 75 FR 17181 (Apr. 5, 2010) and 63388 (Nov. 29, 2010), 75 FR 75522 (Dec. 3, 2010) (CDS clearing by Chicago Mercantile Exchange Inc.); 59527 (Mar. 6, 2009), 74 FR 10791 (Mar. 12, 2009), 61119 (Dec. 4, 2009), 74 FR 65554 (Dec. 10, 2009), 61662 (Mar. 5, 2010), 75 FR 11589 (Mar. 11, 2010) and 63387 (Nov. 29, 2010) 75 FR 75502 (Dec. 3, 2010) (CDS clearing by ICE Trust US LLC); 59164 (Dec. 24, 2008), 74 FR 139 (Jan. 2, 2009) (temporary CDS clearing by LIFFE Administration and Management and LCH.Clearnet Ltd.) (collectively, ''CDS Clearing Exemption Orders''). LIFFE Administration and Management

deemed registered with the Commission solely for the purpose of clearing SB swaps pursuant to the Dodd-Frank Act.[223]

By virtue of the broad definition of the term ''clearing agency'' in section 3(a)(23)(A) of the Exchange Act,[224] certain entities that provide non-CCP clearing agency services with respect to SB swaps would be required to register as a clearing agency under section 17A(b) of the Exchange Act as of the Effective Date.[225] This issue arises for these entities as of the Effective Date, and not before, because prior to such time SB swaps (other than in limited circumstances) were not deemed to be securities. Non-CCP clearing agency services include such services such as trade matching,[226] collateral management,[227] and tear-up/compression services,[228] which are important post-trade processing services for the SB swap markets (''non-CCP clearing agency services''). On March 2, 2011, the Commission proposed exempting certain market participants from the definition of clearing agency as part of its clearing agency standards release.[229] As noted above, the Commission also intends to separately consider temporary relief from section 17A(b) of the Exchange Act[230] for persons that provide non-CCP clearing agency services in connection with SB swaps so that those persons are not required to be registered as a clearing agency on the Effective Date.[231]

Request for Comment:

• Are there any provisions of section 17A of the Exchange Act for which the Commission should grant temporary exemptive relief? Please specify which provisions and provide a detailed explanation of why granting such exemption would be necessary or appropriate in the public interest, and consistent with the protection of investors.

I. Other Amendments to the Federal Securities Laws Relating to Security-Based Swaps.

Table I lists the remaining statutory provisions of Title VII of the Dodd-Frank Act that have not been addressed above.

TABLE I—OTHER AMENDMENTS TO FEDERAL SECURITIES LAWS RELATING TO SECURITY-BASED SWAPS—COMPLIANCE DATES

Exchange act section	Compliance date		Authorizes/directs/limits commission action[232]	Relief granted
	Upon effective date (July 16, 2011)	Upon registration, publication of final rules, or other commission action[233]		
761(a): Amendments to section 3(a) of the Exchange Act[234]—Definitions (other than the definition of substantial position in section 3(a)(67)(B)).[235]	✓			No.[236]
761(a): Amendments to section 3(a) of the Exchange Act[237]—Definition of substantial position in section 3(a)(67)(B).[238]			✓	N/A.
761(b): Authority to further define terms			✓	N/A.
762(a): Repeals section 206B and 206C of the Gramm-Leach-Bliley Act (''GLBA'').[239]	✓			No.
762(b): Section 206A of GLBA: conforming amendment.[240]	✓			No.
762(c): Sections 2A and 17 of the Securities Act: conforming amendments.[241]	✓			No.
762(d): Sections 3A, 9, 10, 15, 16, 20, and 21A of the Exchange Act: conforming amendments.[242]	✓			No.
763(e): Section 6(l) of the Exchange Act: trading in SB swaps.[243]	✓			Yes.

and LCH.Clearnet Ltd. allowed their order to lapse without seeking renewal.

There are currently four clearing agencies authorized to provide CCP services for SB swap transactions pursuant to these orders. Eurex Clearing AG will not be deemed registered as a clearing agency.

[223] *See* section 17A(l) of the Exchange Act, 15 U.S.C. 78q–1(1). To be deemed registered, a clearing agency must be a depository institution that cleared swaps as a multilateral clearing organization or a derivative clearing organization that cleared swaps pursuant to an exemption from registration as a clearing agency. *Id.* Section 17A(l) of the Exchange Act, 15 U.S.C. 78q–1(l), provides that certain SB swap clearing agencies will be deemed registered for the purpose of clearing SB swaps (''Deemed Registered Provision''). Under this Deemed Registered Provision, a deemed registered clearing agency will be required to comply with all requirements of the Exchange Act, and the rules thereunder, applicable to registered clearing agencies, including, for example, the obligation to file proposed rule changes under section 19(b) of the Exchange Act, 15 U.S.C. 78s(b). After the Deemed Registered Provision becomes effective on the Effective Date, *see supra* Table H, certain clearing agencies will no longer need an exemption from registration as a clearing agency under section 17A of the Exchange Act, 15 U.S.C. 78q–1, in order to clear SB swaps. As noted above, ICE Trust U.S. LLC, ICE Clear Europe Limited, and the Chicago Mercantile Exchange Inc., are eligible for the Deemed Registered Provision based on the specified criteria in section 17A(l) of the Exchange Act, 15 U.S.C. 78q–1(l). In addition, to facilitate the operation of clearing agencies as CCPs for eligible CDS, the Commission also adopted interim temporary exemptions (''Temporary Exemptions'') from certain provisions of the Securities Act, the Exchange Act and the Trust Indenture Act, 15 U.S.C. 77aaa *et seq.,* subject to certain conditions. *See* Temporary Exemptions for Eligible Credit Default Swaps to Facilitate Operation of Central Counterparties to Clear and Settle Credit Default Swaps, 74 FR 3967 (Jan. 22, 2009). The Commission extended the expiration date of the final temporary rules until July 16, 2011. *See* Extension of Temporary Exemptions for Eligible Credit Default Swaps to Facilitate Operation of Central Counterparties to Clear and Settle Credit Default Swaps, 75 FR 72660 (Nov. 26, 2010). The Commission is considering extending the Temporary Exemptions. Once extended, the Temporary Exemptions would continue to be available to those clearing agencies that are deemed registered. The Commission also has proposed exemptions that would allow clearing agencies in their function as CCPs to offer or sell SB swaps subject to certain conditions. These proposed exemptions, if adopted, would replace the Temporary Exemptions and would extend to all SB swaps. *See* Proposed Cleared SB Swap Exemptions, *supra* note 19.

[224] 15 U.S.C. 78c(a)(23)(A).

[225] 15 U.S.C. 78q–1(b). As discussed above, the new registration requirement for SB swap clearing agencies in section 17A(g) of the Exchange Act, 15 U.S.C. 78q–1(g), will not apply until at least 60 days after rulemaking is completed.

[226] *See* Clearing Agency Standards for Operation and Governance, *supra* note 10 (discussing trade matching services).

[227] *Id.* (discussing collateral management activities).

[228] *Id.* (discussing tear-up and compression services).

[229] *Id.* at 14494–96 (proposing, under section 36 of the Exchange Act, 15 U.S.C. 78mm, an exemption to certain persons from the definition of clearing agency in section 3(a)(23) of the Exchange Act, 15 U.S.C. 78c(a)(23), and asking questions regarding whether there are other persons for whom the Commission should grant a similar exemption).

[230] 15 U.S.C. 78q–1(b).

[231] *See supra* note 217.

TABLE I—OTHER AMENDMENTS TO FEDERAL SECURITIES LAWS RELATING TO SECURITY-BASED SWAPS—COMPLIANCE DATES—Continued

Exchange act section	Compliance date		Authorizes/directs/limits commission action [232]	Relief granted
	Upon effective date (July 16, 2011)	Upon registration, publication of final rules, or other commission action [233]		
763(f): Amends sections 9(b)(1)–(3) of the Exchange Act to add "security-based swaps". [244]	✓			No.
764(b): Savings clause regarding Federal banking agency authority.			✓ [245]	N/A.
765: Rulemaking on conflicts of interest			✓	N/A.
766(b): Sections 13(d)(1) and (g)(1) of the Exchange Act: beneficial ownership reporting. [246]	✓			No.
766(c): Section 13(f)(1) of the Exchange Act: reports by institutional investment managers. [247]	✓			No.
766(d): Sections 15(b)(4)(C) and (b)(4)(F) of the Exchange Act: administrative proceeding authority. [248]	✓			No.
766(e): Section 13(o) of the Exchange Act: SB swap beneficial ownership. [249]		✓ [250]		No.
767: Section 28(a) of the Exchange Act: state gaming and bucket shop laws. [251]	✓			N/A. [252]
768: Sections 2(a) and 5(d) of the Securities Act: amendments to the Securities Act; treatment of SB swaps. [253]	✓			No. [254]
769: Conforming definition in section 2(a)(54) of the Investment Company Act of 1940. [255]	✓			No.
770: Conforming definition in section 202(a)(29) of the Investment Advisers Act of 1940. [256]	✓			No.
771: Other authority of other agencies	✓			N/A.
772(a): Section 36(c) of the Exchange Act: jurisdiction—in general. [257]	✓			N/A.
772(b): Section 30(c) of the Securities Act: jurisdiction—rule of construction. [258]	✓			N/A.
773: Section 21B(f) of the Exchange Act: civil penalties [259]	✓			N/A.
774: Effective date	✓			N/A.

As indicated in Table I, the Commission finds, pursuant to section 36 of the Exchange Act,[260] that it is necessary or appropriate in the public interest, and is consistent with the protection of investors, to grant a temporary conditional exemption from section 6(l) of the Exchange Act to certain persons.[261] Section 6(l) of the Exchange Act [262] would make it unlawful, as of the Effective Date, for any person to effect a transaction in an SB swap with or for a person that is not an eligible contract participant,[263] unless such transaction is effected on a national securities exchange registered pursuant to section 6(b) of the Exchange Act.[264]

Title VII amended the definition of eligible contract participant in the Commodity Exchange Act.[265] A number

[232] These provisions do not require compliance by market participants on the Effective Date, unless the relevant Commission action already has been undertaken. *See supra* note 26 and accompanying text.

[233] A number of Title VII provisions expressly (or implicitly) apply only to "registered" persons. Until the related registration processes for such persons have been established by final Commission rules, and such persons have become registered pursuant to such rules, they will not be required to comply with these Title VII provisions. If a Title VII provision requires a rulemaking, such provision will not necessarily go into effect on the Effective Date, but instead will go into effect "not less than" 60 days after publication of the related final rule or on July16, 2011, whichever is later. *See* section 774 of the Dodd-Frank Act, 15 U.S.C. 77b note.

[234] 15 U.S.C. 78c(a).

[235] 15 U.S.C. 78c(a)(67)(B).

[236] *See supra* note 22 and accompanying text.

[237] 15 U.S.C. 78c(a).

[238] 15 U.S.C. 78c(a)(67)(B).

[239] 15 U.S.C. 78c note. This amendment, along with the amendments in sections 762(b), (c), and (d) of the Dodd-Frank Act, repeals GLBA, Securities Act, and Exchange Act provisions (as added by the Commodity Futures Modernization Act of 2000) limiting the Commission's authority over security-based swap agreements (as defined in section 206B of the GLBA, 15 U.S.C. 78c note).

[240] *Id.*

[241] 15 U.S.C. 77b–1 and 77q.

[242] 15 U.S.C. 78c-1, 78i, 78j, 78o, 78p, 78t, and 78u–1. *See supra* note 224.

[243] 15 U.S.C. 78f(l).

[244] 15 U.S.C. 78i(b)(1)–(3). Section 763(f) makes conforming amendments to the Exchange Act.

[245] Section 764(b) provides that no appropriate Federal banking agency shall be divested of any authority for any entity over which it has authority.

[246] 15 U.S.C. 78m(d)(1) and (g)(1).

[247] 15 U.S.C. 78m(f)(1).

[248] 15 U.S.C. 78o(b)(4)(C) and (b)(4)(F).

[249] 15 U.S.C. 78m(o).

[250] *See* Beneficial Ownership Reporting Requirements and Security-Based Swaps, Exchange Act Release No. 64628 (June 8, 2011), *available at http://www.sec.gov/rules/final/2011/34–64628.pdf.*

[251] 15 U.S.C. 78bb(a).

[252] This section limits the scope of applicability of certain provisions of the Exchange Act and addresses certain state law issues.

[253] 15 U.S.C. 77b(a) and 77e(d).

[254] The Commission has proposed exemptions from the registration requirements of the Securities Act for offers or sales of SB swaps issued by certain clearing agencies satisfying certain conditions. *See* Proposed Cleared SB Swap Exemptions, *supra* note 19.

[255] 15 U.S.C. 80a–2(a)(54). Section 769 of the Dodd-Frank Act makes conforming amendments to section 2(a)(54) the Investment Company Act of 1940.

[256] 15 U.S.C. 80b–2(a)(29). Section 770 of the Dodd-Frank Act makes conforming amendments to section 202(a)(2) of the Investment Advisers Act of 1940.

[257] 15 U.S.C. 78mm(c).

[258] 15 U.S.C. 78dd(c).

[259] 15 U.S.C. 78u–2(f).

[260] 15 U.S.C. 78mm.

[261] 15 U.S.C. 78f(l).

[262] *Id.*

[263] *See* section 1a(18) of the Commodity Exchange Act, 7 U.S.C. 1a(18).

[264] 15 U.S.C. 78f(b).

[265] Section 721(a) of the Dodd-Frank Act amended section 1a(18) of the Commodity Exchange Act, 7 U.S.C. 1a(18), to include a new definition of the term "eligible contract participant."

of commenters have raised concerns about potential uncertainty regarding the definition of ''eligible contract participant'' as a result of the Title VII amendments to that definition.[266] They have suggested, among other things, that market participants may cease or limit their business with counterparties that could potentially be considered non-eligible contract participants when the Dodd-Frank Act amendments to the definition of eligible contract participant go into effect.[267]

The Commission finds that temporary exemption from section 6(l) of the Exchange Act[268] for persons that meet the definition of eligible contract participant as set forth in section 1a(12) of the Commodity Exchange Act (as in effect on July 20, 2010)[269] is necessary or appropriate in the public interest, and is consistent with the protection of investors, because it would allow persons currently participating in the SB swap markets that could potentially be considered non-eligible contract participants under the definition of eligible contract participant as amended by Title VII of the Dodd-Frank Act, to continue to do so until the term eligible contract participant is further defined in final rulemaking. Accordingly, the Commission is providing a temporary conditional exemption pursuant to section 36 of the Exchange Act[270] from section 6(l) of the Exchange Act[271] for eligible contract participants under current law. The temporary exemption will expire on the effective date for the final rules further defining the term eligible contract participant.

In addition, the Commission has received comments[272] expressing concern regarding the implication of the incorporation of SB swaps into the definition of ''security.''[273] Commenters have indicated that they are still analyzing the full implication of such expansion of the definition of security, but that it will take time.[274] Market participants therefore have requested temporary relief from certain provisions of the Exchange Act that will impose new obligations on counterparties to SB swaps so that they may complete their analysis and submit requests for more targeted relief.[275] The Commission intends to separately address relief in this area.[276]

Moreover, the Commission has proposed exemptions under the Securities Act, the Exchange Act, and the Trust Indenture Act for SB swaps issued by certain clearing agencies satisfying certain conditions.[277] The proposed exemptive rules would exempt transactions by clearing agencies in these SB swaps from all provisions of the Securities Act, other than the section 17(a)[278] antifraud provisions, as well as exempt these SB swaps from Exchange Act registration requirements and from the provisions of the Trust Indenture Act, provided certain conditions are met.[279]

Request for Comment:

- Is the temporary exemption from section 6(l) of the Exchange Act appropriate? If not, why not? Is the condition that transactions be limited to eligible contract participants as defined under current law sufficient to protect SB swap market participants that would otherwise receive the protection of the exchange-trading requirement of section 6(l) of the Exchange Act?
- Are there any provisions set out in Table I above, other than those for which the Commission has indicated that it will be providing guidance, and where appropriate, temporary relief, for which the Commission should grant temporary exemptive relief? Please specify which provisions and provide a detailed explanation of why granting such exemption would be necessary or appropriate in the public interest, and consistent with the protection of investors.

J. Section 29(b) of the Exchange Act

Section 29(b) of the Exchange Act generally provides that contracts made in violation of any provision of the Exchange Act, or the rules thereunder, shall be void ''(1) as regards the rights of any person who, in violation of any such provision, * * * shall have made or engaged in the performance of any such contract, and (2) as regards the rights of any person who, not being a party to such contracts, shall have acquired any right thereunder with actual knowledge of the facts by reason of which the making or performance of such contracts in violation of any such provision * * *.''[280] As discussed above, the Commission does not believe that provisions of Title VII for which the Commission has taken the view that compliance will either be triggered by registration of a person or by adoption of final rules by the Commission, or for which the Commission has provided an exception or exemptive relief herein, require compliance as of the Effective Date. The Commission thus does not believe that section 29(b) of the Exchange Act[281] would apply to such provisions. For the avoidance of doubt, however, and to avoid possible legal uncertainty or market disruption, the Commission is granting temporary exemptive relief from section 29(b) of the Exchange Act.[282]

The Commission is exercising its authority under section 36 of the Exchange Act[283] to temporarily exempt any SB swap contract entered into on or after the Effective Date from being void or considered voidable by reason of section 29 of the Exchange Act[284] because any person that is a party to the SB swap contract violated a provision of the Exchange Act that was amended or added by subtitle B of Title VII of the Dodd Frank Act and for which the Commission has taken the view that compliance will be triggered by registration of a person or by adoption of final rules by the Commission, or for which the Commission has provided an exception or exemptive relief herein,

[266] *See, e.g.,* Trade Association Letter, *supra* note 28 (''The definition of [eligible contract participant] was amended by [the Dodd-Frank Act], and the [Commission and the CFTC] have sought comments in [the Entity Definitions Release] on how to further define such term, including how to interpret the phrase ''discretionary basis.'' Until the term [eligible contract participant] is further defined in a final rulemaking, market participants will not know whether they are dealing with an [eligible contract participant], and where the line is between their institutional and retail businesses. As a result, they will not know * * * whether certain transactions are subject to the new requirement for [non-eligible contract participant] transactions to be executed on an exchange * * *. As a result, market participants may cease or severely limit their business with counterparties that could potentially be considered [non-eligible contract participants] under the Dodd-Frank statutory definition of [eligible contract participant].'').

[267] *Id.*

[268] 15 U.S.C. 78(f)(l).

[269] 7 U.S.C. 1a(12) (as in effect on July 20, 2010).

[270] 15 U.S.C. 78mm.

[271] 15 U.S.C. 78f(l).

[272] *See supra* note 28.

[273] The Commission notes however that it has not received any comments regarding the definition of ''security future'' or the possibility that SB swaps may be characterized as security futures. Section 3(a)(55) of the Exchange Act, 15 U.S.C. 78c(a)(55), excludes from the definition of security future ''any agreement, contract, or transaction excluded from the Commodity Exchange Act under section 2(c), 2(d), 2(f), or 2(g) of the Commodity Exchange Act (as in effect on the date of enactment of the Commodity Futures Modernization Act of 2000) or title IV of the Commodity Futures Modernization Act of 2000.'' Although the Dodd-Frank Act repealed certain provisions of the Commodity Exchange Act added by the CFMA, Title VII did not affect this exclusion or otherwise affect the legal certainty provided by section 3(a)(55) of the Exchange Act regarding the potential scope of the definition of security future.

[274] *See supra* note 28 and note 275.

[275] See Trade Association Letter, *supra* note 28.

[276] *See supra* note 22 and accompanying text.

[277] *See* Proposed Cleared SB Swap Exemptions, *supra* note 19 and discussion *supra* note 223.

[278] 15 U.S.C. 77q(a).

[279] *See* Proposed Cleared SB Swap Exemptions, *supra* note 19.

[280] 15 U.S.C. 78cc(b).

[281] *Id.*

[282] *Id.*

[283] 15 U.S.C. 78mm.

[284] 15 U.S.C. 78cc(b).

until such date as the Commission specifies.

The Commission finds that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors, because the legal uncertainty that could result if contracts entered into after the Effective Date were void or voidable under section 29(b) of the Exchange Act [285] could be disruptive to the financial markets, create confusion for both financial institutions and their customers, or result in unnecessary and wasteful litigation.

As previously discussed, once the relevant provisions of the Dodd-Frank Act take effect,[286] persons effecting transactions in SB swaps, or engaged in acts, practices, and courses of business involving SB swaps, will be subject to the general antifraud and anti-manipulation provisions of the Federal securities laws that were in place before the enactment of the Dodd-Frank Act, including sections 9(a) and 10(b) of the Exchange Act,[287] rule 10b–5 thereunder [288] (and the prohibitions against insider trading), section 15(c) of the Exchange Act,[289] and section 17(a) of the Securities Act,[290] among others. Persons would retain all available rights as a result of any violation of these general antifraud and anti-manipulation provisions.

III. Solicitation of Comments

The Commission intends to monitor closely the transition of the derivatives markets to regulated markets and to determine to what extent, if any, additional regulatory action may be necessary. The Commission is soliciting public comment on all aspects of these exemptions and the guidance it provided regarding compliance dates, including:

1. Is the guidance provided in this section useful, appropriate, and sufficient for persons to determine which amendments to the Exchange Act by Title VII require compliance on July 16, 2011? If not, please explain and provide examples of which provisions require additional guidance.

2. Are there other provisions of the Exchange Act as amended by the Dodd-Frank Act for which temporary exemptive relief should be granted? Please provide section references and provide a detailed explanation of why granting such an exemption would be necessary or appropriate in the public interest, and consistent with the protection of investors.

3. Is the duration of the temporary exemptions granted in this Order appropriate? If not, for which exemptions are the duration not appropriate and what should be the appropriate duration?

4. Should any conditions be placed on any of these exemptions? If so, which exemptions? Please explain and provide specific examples.

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Comments may be submitted by any of the following methods:

IV. Temporary Exemptions and Other Temporary Relief

For the reasons discussed above in Part II, the Commission is granting the following temporary relief:

It is hereby ordered, pursuant to section 36 of the Securities Exchange Act of 1934, that no reporting party (as defined in 17 CFR 242.900) shall be required to report any pre-enactment security-based swap (as defined in 17 CFR 242.900) under section 3C(e)(1) of the Securities Exchange Act of 1934 until the date six (6) months after the date a security-based swap data repository that is capable of accepting the asset class (as defined in 17 CFR 242.900) of such security-based swap is registered by the Commission.

It is hereby further ordered, pursuant to section 36 of the Securities Exchange Act of 1934, that security-based swap dealers and major security-based swap participants are exempt from the requirements of section 3C(g)(5)(B) of the of the Securities Exchange Act of 1934 until the earliest compliance date set forth in any of the final rules regarding section 3C(b) of the Securities Exchange Act of 1934.

It is hereby further ordered, pursuant to section 36 of the Securities Exchange Act of 1934, that registered clearing agencies under section 17A of the Securities Exchange Act of 1934 are exempt from the requirements of sections 3C(j)(1) and (2) of the of the Securities Exchange Act of 1934 until the earliest compliance date set forth in any of the final rules regarding section 3C(j)(2) of the Securities Exchange Act of 1934.

It is hereby further ordered, pursuant to section 36 of the Securities Exchange Act of 1934, that persons that operate a facility for the trading or processing of security-based swaps that is not currently registered as a national securities exchange or that cannot yet register as a security-based swap execution facility because final rules for such registration have not yet been adopted are exempt from the requirements of section 3D(a)(1) of the Securities Exchange Act of 1934 until the earliest compliance date set forth in any of the final rules regarding registration of security-based swap execution facilities.

It is hereby further ordered, pursuant to section 36 of the Securities Exchange Act of 1934, that registered clearing agencies under section 17A of the Securities Exchange Act of 1934 are exempt from the requirements of section 3D(c) of the Securities Exchange Act of 1934 until the earliest compliance date set forth in any of the final rules regarding registration of security-based swap execution facilities.

It is hereby further ordered, pursuant to section 36 of the Securities Exchange Act of 1934, that security-based swap dealers and major security-based swap participants are exempt from the requirements of section 3E(f) of the Securities Exchange Act of 1934 until the date upon which the rules adopted by the Commission to register security-based swap dealers and major security-based swap participants become effective.

It is hereby further ordered, pursuant to section 36 of the Securities Exchange Act of 1934, that entities that meet the definition of security-based swap data repository as set forth in section 3(a)(75) of the Securities Exchange Act of 1934 are exempt from requirements of sections 13(n)(5)(D)(i), 13(n)(5)(F), 13(n)(5)(G), 13(n)(5)(H), and 13(n)(7)(A) through (C) of the Securities Exchange Act of 1934 until the earlier of (1) the date the Commission grants registration to the security-based swap data repository and (2) the earliest compliance date for any of the final rules regarding the registration of security-based swap data repositories.

It is hereby further ordered, pursuant to section 15F(b)(6) of the Securities Exchange Act of 1934, that security-based swap dealers and major security-based swap participants are temporarily excepted from the prohibition of section 15F(b)(6) of the Securities Exchange Act of 1934 with respect to persons subject to a statutory disqualification (as defined in section 3(a)(39) of the Securities Exchange Act of 1934) who are currently associated with a security-based swap dealer or major security-based swap participant and who effect or are involved in effecting security-based swaps on behalf of such security-based swap dealer or major security-based swap participant until the date upon which rules adopted by the Commission to register security-based

[285] *Id.*

[286] *See* section 774 of the Dodd-Frank Act.

[287] 15 U.S.C. 78i(a) and 78j(b).

[288] 17 CFR 240.10b–5.

[289] 15 U.S.C. 78o(c).

[290] 15 U.S.C. 77q(a).

swap dealers and major security-based swap participants become effective.

It is hereby further ordered, pursuant to section 36 of the Securities Exchange Act of 1934, that any person that meets the definition of eligible contract participant as set forth in section 1a(12) of the Commodity Exchange Act (as in effect on July 20, 2010) is exempt from the requirements of section 6(l) of the Securities Exchange Act of 1934 with respect to a transaction in a security-based swap until the effective date for the final rules further defining the term eligible contract participant, provided that such person effects such transaction with or for a person that also meets the definition of eligible contract participant as set forth in section 1a(12) of the Commodity Exchange Act (as in effect on July 20, 2010).

It is hereby further ordered, pursuant to section 36 of the Securities Exchange Act of 1934, that no contract entered into on or after July 16, 2011 shall be void or considered voidable by reason of section 29(b) of the Securities and Exchange Act of 1934 because any person that is a party to the contract violated a provision of the Securities Exchange Act of 1934 that was amended or added by subtitle B of the Wall Street Transparency and Accountability Act of 2010 and for which the Commission has taken the view that compliance will be triggered by registration of a person or by adoption of final rules by the Commission, or for which the Commission has provided an exception or exemptive relief herein, until such date as the Commission specifies.

By the Commission.

Dated: June 15, 2011.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–15432 Filed 6–21–11; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 333

[Docket No. FDA–2011–D–0404]

Guidance for Industry on Topical Acne Drug Products for Over-the-Counter Human Use—Revision of Labeling and Classification of Benzoyl Peroxide as Safe and Effective; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for small business entities entitled ''Topical Acne Drug Products for Over-the-Counter Human Use—Revision of Labeling and Classification of Benzoyl Peroxide as Safe and Effective.'' This guidance is intended to help small businesses understand and comply with the requirements of the final rule that adds benzoyl peroxide as a generally recognized as safe and effective (GRASE) active ingredient in over-the-counter (OTC) topical acne drug products and provides new labeling requirements applicable to all OTC topical acne products marketed under the monograph (75 FR 9767, March 4, 2010) (final rule). The guidance describes the requirements of the final rule in plain language and provides answers to common questions on how to comply with the rule. This guidance was prepared in accordance with the Small Business Regulatory Fairness Act.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Arlene H. Solbeck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5426, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for small business entities entitled ''Topical Acne Drug Products for Over-the-Counter Human Use—Revision of Labeling and Classification of Benzoyl Peroxide as Safe and Effective; Small Entity Compliance Guide.'' This guidance summarizes the March 4, 2010, final rule regarding topical acne drug products for OTC use that makes the following changes to the OTC regulations:

- Adds benzoyl peroxide as a GRASE active ingredient in OTC topical acne drug products.
- Sets forth new warnings and a direction that must be included in labeling of OTC topical acne drug products that contain benzoyl peroxide.
- Revises labeling requirements for all OTC topical acne drug products to ensure consistency with the standardized drug facts formatting and requirements set forth in § 201.66 (21 CFR 201.66).

The guidance summarizes in table form the requirements for specific warnings and directions in the labeling that apply to all OTC acne drug products marketed under the monograph (*i.e.,* products that contain any of the active ingredients permitted under the OTC topical acne drug monograph, including benzoyl peroxide, resorcinol, resorcinol monoacetate, salicylic acid, and/or sulfur) (21 CFR part 333, subpart D)). The summaries include new warnings and a new ''direction for use'' required specifically for OTC topical acne products that contain benzoyl peroxide. The revised labeling requirements ensure that the labeling of OTC topical acne drug products is consistent with the standardized drug facts labeling content and format requirements in § 201.66.

FDA is issuing this small entity compliance guide as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the classification of benzoyl peroxide as GRASE in the OTC topical acne drug monograph, and revised labeling requirements for OTC topical acne products, as set forth in the final rule. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: June 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–15560 Filed 6–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2011–0540]

RIN 1625–AA08

Special Local Regulation for Marine Events; Temporary Change of dates for Recurring Marine Events in the Fifth Coast Guard District; Mill Creek, Hampton, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard will temporarily change the enforcement period of one special local regulation for recurring marine events in the Fifth Coast Guard District. This regulation applies a hydroplane speed boat race which was originally scheduled for August 12–14, 2011 will be on August 6–7, 2011. This regulation will restrict vessel traffic in portions of Mill Creek in Hampton, Virginia during the rescheduled event to protect mariners and the boating public from the potential hazards associated with hydroplane speed boats that will reach speeds in excess of 150 miles per hour.

DATES: This rule is effective from August 6, 2011, through August 15, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0540 and are available online by going to *http://www.regulations.gov*, inserting USCG–2011–0540 in the ''Keyword'' box, and then clicking ''Search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail LCDR Christopher A. O'Neal, Waterways Management Division Chief, Sector Hampton Roads, Coast Guard; telephone 757–668–5580, e-mail *Christopher.A.ONeal@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

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 delaying the effective date would be contrary to the public interest since immediate action is needed to ensure the safety of the event participants, patrol vessels, spectator craft and other vessels transiting the event area. The potential dangers posed by hydroplane speed boats, operating in speeds excess of 150 miles per hour, make special local regulations necessary. However, the Coast Guard will provide advance notifications to users of the effected waterways via marine information broadcasts, local notice to mariners, commercial radio stations and area newspapers. This regulation represents the re-scheduling of the event in order to de-conflict the event from another race that many competitors and a sponsor are involved in during the second weekend in August 2011 and to have the event take place close in time to the regularly scheduled dates of the event. In addition, publishing an NPRM is unnecessary because this event is an annual event which mariners should be aware of taking place, as it is noticed in the **Federal Register**. If mariners had concerns about this event taking place, they are on notice throughout the year of the event and can object to or comment about the event at any time. When the NPRM, including the table to § 100.501 listing all of the annual events, was made available for comment, there were no objections to this event.

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**. Delaying the effective date would be contrary to the public interest since immediate action is needed to ensure the safety of the event participants, patrol vessels, spectator craft and other vessels transiting the event area. The potential dangers posed by hydroplane speed boats, operating in speeds excess of 150 miles per hour, make special local regulations necessary. However, the Coast Guard will provide advance notifications to users of the effected waterways via marine information broadcasts, local notice to mariners, commercial radio stations and area newspapers. This regulation represents the re-scheduling of the event in order to de-conflict the event from another race that many competitors and a sponsor are involved in during the second weekend in August 2011 and to have the event take place close in time to the regularly scheduled dates of the event. In addition, publishing an NPRM is unnecessary because this event is an annual event which mariners should be aware of taking place, as it is noticed in the **Federal Register**. If mariners had concerns about this event taking place, they are on notice throughout the year of the event and can object to or comment about the event at any time. When the NPRM, including the table to § 100.501 listing all of the annual events, was made available for comment, there were no objections to this event.

Background and Purpose

This event is annually held in August, scheduled to begin on the second Friday of August and anticipated to run through the Saturday and Sunday of that weekend. The regulation listing annual marine events within the Fifth Coast Guard District and their regulated dates is 33 CFR 100.501. A table to § 100.501 identifies marine events by Captain of the Port zone. This particular event, sponsored this year by the City of Hampton, Hampton Cup Regatta Racing Club and the Phoebus Civic Association, is listed at line No. 44.

This year, the Regatta was initially scheduled to take place on August 12–14, 2011. However, the event was rescheduled to take place one week earlier, on August 6–7, 2011. The date has changed due to participants and a sponsor being involved in another race during the second weekend in August. In order to deal with this conflict, the regatta date was pushed up one weekend in August 2011.

On August 6–7, 2011, the City of Hampton, Hampton Cup Regatta Racing Club and the Phoebus Civic Association will sponsor the ''85th Hampton Cup Regatta'' in the waters of Mill Creek, adjacent to Fort Monroe, Hampton, Virginia. The event will consist of approximately 75–100 hydroplane powerboats conducting high-speed competitive races in heats counter-clockwise around an oval racecourse on the water of the Mill Creek adjacent to Fort Monroe, Hampton, Virginia and Route 258 Mercury Highway Bridge. A fleet of spectator vessels is expected to gather near the event site to view the competition. Due to the need for vessel control during the event, the Coast Guard will temporarily restrict vessel traffic in the event area to provide for the safety of participants, spectators, and other transiting vessels. The special local regulation will be enforced from 11:30 a.m. to 5 p.m. August 6, 2011 and from 11:30 a.m. to 5 p.m. on August 7, 2011.

During this enforcement period, vessels may not enter the regulated area unless they receive permission from the Coast Guard Patrol Commander.

Discussion of Rule

The Coast Guard will temporarily suspend the regulation listed at line No. 44 in Table to § 100.501 and will insert this new temporary regulation at Table to § 100.501 line No. 44a, in order to reflect the change in date for this event this year. This change is needed to accommodate the conflict in races during the second weekend in August 2011; because there is another race that many participants and a sponsor are involved with during the second week of August 2011, it was determined to shift the ''85th Hampton Cup Regatta'' to the first weekend in August 2011. No other portion of the Table to § 100.501 shall be affected by this regulation.

This special local regulation will restrict navigation in the regulated area during the marine event, from 11:30 a.m. to 5 p.m. on August 6, 2011 and from 11:30 a.m. to 5 p.m. on August 7, 2011. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area during the effective period. The regulated area is needed to control vessel traffic during the event to enhance the safety of participants in and spectators to the 85th Hampton Cup Regatta.

The enforcement period for this special local regulation will be from 11:30 a.m. to 5 p.m. on August 6, 2011 and from 11:30 a.m. to 5 p.m. on August 7, 2011. The Coast Guard, at its discretion, will allow the passage of vessels when races are not taking place. Except for participants and vessels authorized by the Captain of the Port or his Representative, no person or vessel may enter or remain in the regulated area.

In addition to notice in the **Federal Register**, the maritime community will be provided advance notification via the Local Notice to Mariners and marine information broadcasts.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

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 that Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under that those Orders. Although this rule prevents traffic from transiting a portion of certain waterways during specified events, the effect of this regulation will not be significant due to the limited duration that the regulated area will be in effect and the extensive advance notifications that will be made to the maritime community via marine information broadcasts, local radio stations and area newspapers so mariners can adjust their plans.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

The rule would affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit or anchor in this section of Mill Creek during the event from 11:30 a.m. to 6 p.m. on August 6 and from 11:30 a.m. to 6 p.m. on August 7, 2011.

Although this regulation prevents traffic from transiting a portion of Mill Creek during the event, this rule would not have a significant economic impact on a substantial number of small entities for the following reasons. This rule would be in effect for only a limited period. Vessel traffic will be able to transit the regulated area between heats, when the Coast Guard Patrol Commander deems it is safe to do so. Before the enforcement period, the Coast Guard will issue maritime advisories so mariners can adjust their plans accordingly.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

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.

Collection of Information

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

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed

this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or Tribal government, in the aggregate, or by the private sector of $100,000,000 (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.

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.

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

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

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

Environment

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 is categorically excluded, under figure 2–1, paragraph (34)(h), of the Instruction. This rule involves implementation of regulations within 33 CFR Part 100 that apply to organized marine events on the navigable waters of the United States that may have potential for negative impact on the safety or other interest of waterway users and shore side activities in the event area. The category of water activities includes but is not limited to sail boat regattas, boat parades, power boat racing, swimming events, crew racing, and sail board racing. Under figure 2–1, paragraph (34)(h), of the Instruction, an environmental analysis checklist and a categorical exclusion determination will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Suspend line No. 44 in the Table to § 100.501.

■ 3. Add line No. 44a in Table to § 100.501 to read as follows:

§ 100.501. Special Local Regulations; Marine Events in the Fifth Coast Guard District.

* * * * *

TABLE TO § 100.501—ALL COORDINATES LISTED IN THE TABLE TO § 100.501 REFERENCE DATUM NAD 1983

Number	Date	Event	Sponsor	Location		
*	*	*	*	*	*	*
Coast Guard Sector Hampton Roads—COTP Zone						

TABLE TO § 100.501—ALL COORDINATES LISTED IN THE TABLE TO § 100.501 REFERENCE DATUM NAD 1983—Continued

Number	Date	Event	Sponsor	Location
*	*	*	*	*
44a	August 6–7, 2011	Hampton Cup Regatta	City of Hampton, Hampton Cup Regatta Racing Club, and the Phoebus Civic Association.	The waters of Mill Creek, adjacent to Fort Monroe, Hampton, Virginia, enclosed by the following boundaries: to the north, a line drawn along latitude 37°01′00″ N, to the east a line drawn along longitude 076°18′30″ W, to the south a line parallel with the shoreline adjacent to Fort Monroe, and the west boundary is parallel with the Route 258—Mercury Boulevard Bridge.
*	*	*	*	*

Dated: June 13, 2011.

Mark S. Ogle,

Captain, U.S. Coast Guard, Captain of the Port Hampton Roads.

[FR Doc. 2011–15619 Filed 6–21–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2011–0103]

RIN 1625–AA08

Special Local Regulation; Extreme Sailing Series Boston; Boston Harbor, Boston, MA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation in Boston Harbor, Boston, Massachusetts, within the Captain of the Port (COTP) Boston Zone. This special local regulation is necessary to provide for the safety of life on navigable waters during the Extreme Sailing Series Boston regatta. The special local regulation will temporarily restrict vessel traffic in a portion of Boston Harbor, and prohibit vessels not participating in the Extreme Sailing Series event from entering the designated race area.

DATES: This rule is effective from 1 p.m. on June 30, 2011, to 6 p.m. on July 4, 2011. This regulation will also be enforced daily from 1 p.m. until 6 p.m., June 30, 2011 through July 4, 2011.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2011–0103 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–0103 in the ''Keyword'' box, and then clicking ''Search.'' This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail MST1 David Labadie of the Waterways Management Division, U.S. Coast Guard Sector Boston; telephone 617–223–3010, e-mail *david.j.labadie@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On April 13, 2011, we published a notice of proposed rulemaking (NPRM) entitled: Special Local Regulation; Extreme Sailing Series Boston; Boston Harbor, Boston, Massachusetts, in the **Federal Register** (76 FR 20595). We received one comment on the proposed rule. No public meeting was requested, and none was held.

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**. The Coast Guard completed the public comment period for this rule and only received one comment on the rule which was positive in nature. The sponsor is unable to reschedule this event due the vast number of participants, scheduling, and to other activities being held in conjunction with the event. Establishing a special local regulation for the event will help ensure the safety of persons and property and minimize the associated risks by controlling vessel traffic and movement.

Basis and Purpose

The legal basis for this rule is 33 U.S.C. 1233, which authorizes the Coast Guard to define Special Local Regulations.

Establishing a special local regulation for the event will help ensure the safety of persons and property and minimize the associated risks by controlling vessel traffic and movement.

Background

This temporary special local regulation is necessary to ensure the safety of vessels, participants, and the public during the Extreme Sailing Series Boston regatta. The event will take place over the course of five days in Boston Harbor in the vicinity of Fan Pier. There will be two regulated areas associated with this event and they will be enforced immediately before, during, and after the regatta, from June 30th through July 4th, 2011, from 1 p.m. to 6 p.m. daily.

This rule is necessary to ensure the safety of vessels and spectators from the hazards associated with competitive sailing regattas. Without the rule, the combination of a large number of recreational vessels due to spectators, sailboats traveling at high speeds on the race course, and large numbers of spectators on the adjacent Fan Pier in close proximity to the water and in a small area of water, could easily result in serious injuries or fatalities.

All persons and vessels shall comply with the instructions of the COTP Boston or the designated on-scene representative. Entering into, transiting through, mooring or anchoring within the special local regulation area is prohibited unless authorized by the COTP Boston or the designated on-scene representative.

Discussion of Comments and Changes

We received one comment and no changes have been made to the proposed rule.

The Boston Harbor Association, a non-profit, public interest organization, stated they attended two meetings regarding the plans for the Extreme Sailing Series. Having been at both meetings, the Boston Harbor Association believes that the proposed regulation restricting access to a portion of the waterway addresses the concerns discussed at the meetings, and write in support of the regulation as drafted. The Boston Harbor Association commends all parties for working together to promote activities which allow the public to enjoy Boston Harbor and the waterfront while minimizing impacts to port commerce and commercial boat operators.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Executive Order 12866 and Executive Order 13563

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, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

The Coast Guard determined that this rule is not a significant regulatory action for the following reasons: (1) The rule will be in effect for five hours per day for five days; (2) persons and vessels may still enter, transit through, anchor in, or remain within the regulated area if they obtain permission from the COTP or the designated representative; and (3) advance notification will be made to the maritime community via broadcast notice to mariners and Local Notice to Mariners (LNM).

Small Entities

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this 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 enter, transit through, anchor in or remain within this regulated area during periods of enforcement.

This rule will not have a significant economic impact on a substantial number of small entities for the following reasons: This rule will be enforced for a short duration and the race area within the Special Local Regulation area can be quickly collapsed at the discretion of the COTP, as necessary to allow for certain vessels greater than 65 feet in length to transit, provided the vessels have given a five-hour advance notice of their intended transit to the COTP. All other vessels not required to provide advance notification may transit within the Special Local Regulation area, with the exception of the race area, at all times while following the regulations in this rule.

Additionally, the race organizers will coordinate with industry and the Boston Pilots to provide minimal interruption of commercial vessel traffic during the enforcement periods.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), in the NPRM we offered to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking.

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.

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or Tribal government, in the aggregate, or by the private sector of $100,000,000 (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.

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.

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

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

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

Environment

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 that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(h), of the Instruction. This rule involves the establishment of a special local regulation. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 100

Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—REGULATED SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add § 100.T01–0103 to read as follows:

§ 100.T01–0103 Special Local Regulation; Extreme Sailing Series Boston; Boston Harbor; Boston, MA.

(a) *Regulated Area.* The following is designated as the special local regulation area: All waters of Boston Harbor near Boston, MA, surface to bottom, encompassed by an area starting at position: 42°21.3′ N; 071°3′ W, thence crossing the Fort Point Channel along Northern Avenue to position 42°21.3′ N; 071°2.9′ W, continuing Southeast along the Shoreline past Fan Pier to the end of the North Jetty at position 42°20.8′ N; 071°1.4′ W, continuing and crossing Boston Harbor to the opposite shore near Logan Airport at position 42°21.2′ N; 071°1′ W, continuing Northwest in a straight line along the shoreline to Pier One at position 42°21.9′ N; 071°02.5′ W, thence back across Boston Harbor to the point of origin at position 42°21.3′ N; 071°3′ W.

(1) The following area within the special local regulation area is specified as the race area: All waters of Boston Harbor near Boston, MA, surface to bottom, encompassed by an area starting at position: 42°21.59′ N; 071°02.52′ W, thence to position 42°21.28′ N; 071°01.83′ W, thence to position 42°21.10′ N; 071°01.95′ W, thence to position 42°21.20′ N; 071°02.26′ W, thence to position 42°21.15′ N; 071°02.31′ W, thence to position 42°21.31′ N; 071°02.72′ W, thence to the point of origin at position 42°21.59′ N; 071°02.52′ W. This area will be clearly defined by floating buoys and will have the ability to be collapsed quickly to allow for safe passage of traffic if they have obtained permission from the COTP or the designated representative.

(b) *Regulations.* In accordance with the general regulations in 33 CFR Part 100, to enter, transit through, anchor in, or remain within the special local regulation area is prohibited unless permission has been authorized by the Captain of the Port (COTP) Boston, or the designated on-scene representative. The ''designated on-scene representative'' is any Coast Guard commissioned, warrant, or petty officer who is designated by the COTP to act on his behalf. The designated on-scene representative will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The COTP or the designated on scene representative may be contacted via VHF Channel 16 or by telephone at (617) 223–5750.

(1) The following restrictions apply to the special local regulation area identified in section (a)(1) of this regulation.

(i) Special Anchorage ''A'', which is a small vessel anchorage located near Rowes Wharf, is the only permitted area for anchoring. All other anchoring within this special local regulation area, including in Anchorage Area #1, is prohibited.

(ii) This special local regulation area is designed to restrict vessel traffic, including all non-motorized vessels, except as may be permitted by the COTP Boston or the designated on-scene representative.

(iii) Within this area all vessels will transit at the minimum speed necessary to maintain headway without creating a wake.

(iv) Due to the waterway area restriction and the expected increase in recreational vessels in the area, vessel operators of all vessels 65 feet in length or greater desiring to enter or operate within the special local regulation area shall contact the COTP or the designated on-scene representative at least five hours prior to the desired transit time to obtain permission to do so. Permission to enter the special local regulation area will be considered on a case by case basis at the discretion of the COTP and vessels may be escorted through the area if the COTP deems it necessary for safe transit. Failure to provide notification of entry at least five hours prior to transit may result in a denial of entry into the regulated area during the enforcement period. Vessel operators given permission to enter the area must comply with all directions given to them by the COTP or the designated on-scene representative.

(2) The following restrictions apply to the area identified as the race area in section (a)(2) of this regulation. This area is closed to all vessel traffic, with the exception of vessels involved directly with the event such as: sailboat race participants, event safety vessels, on-scene patrol and law enforcement vessels.

(c) *Effective Period.* This regulation is effective from 1 p.m. on June 30, 2011, to 6 p.m. on July 4, 2011. This regulation will also be enforced daily

from 1 p.m. until 6 p.m., June 30, 2011 through July 4, 2011.

Dated: June 10, 2011.

John N. Healey,

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

[FR Doc. 2011–15584 Filed 6–21–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0434]

RIN 1625–AA00

Safety Zone; Mile Marker 98.5 West of Harvey Lock Gulf Intracoastal Waterway to Mile Marker 108.5 West of Harvey Lock Gulf Intracoastal Waterway

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone imposing restrictions on the Gulf Intracoastal Waterway (GIWW) between West Harvey Lock Gulf West (WHL) mile marker 98.5 to 108.5. All vessels are prohibited from transiting the zone except as specifically authorized by the Captain of the Port or a designated representative. This temporary safety zone is needed to protect the general public, levee system, vessels and tows from destruction, loss or injury due to hazards associated with rising flood water.

DATES: Effective Date: This rule is effective in the CFR from June 22, 2011 until 11:59 p.m. July 31, 2011. This rule is effective with actual notice for purposes of enforcement beginning 12:01 a.m. May 26, 2011 through 11:59 p.m. July 31, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0434 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–0434 the ''Keyword'' box, and then clicking ''Search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail Lieutenant (LT) Russell Pickering, Coast Guard; telephone 985–380–5334, e-mail *russell.t.pickering@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

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 publishing a NPRM would be impracticable since immediate action is needed to protect the general public, levee system, vessels and tows from the hazards associated with rising flood water.

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**. Providing 30 days notice and delaying its effective date would be impracticable since immediate action is needed to protect the general public, levee system, vessels and tows from destruction, loss or injury due to the hazards associated with rising flood water.

Basis and Purpose

Captain of the Port Morgan City, Louisiana has determined that there is a need to impose temporary safety restrictions for navigation on certain waterways due to unprecedented high water in conjunction with flood control and protection operations by the Army Corps of Engineers.

Discussion of Rule

The Coast Guard is establishing a temporary safety zone imposing restrictions on the Gulf Intracoastal Waterway (GIWW) between West Harvey Lock Gulf West (WHL) mile markers (MM) 98.5 to 108.5 applicable to all commercial traffic. This will affect all East-West traffic through Morgan City on the GIWW. Vessels and tows may not enter this zone unless authorized by the Captains of the Port Morgan City.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

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

Although this regulation will restrict access to the area, the effect of the rule will not be significant because notifications to the marine community will be made through broadcast notice to mariners, Local Notice to Mariners and Marine Safety Information Bulletins. Vessels and tows may request permission and comply with the necessary restrictions from the Captain of the Port Morgan City, or a designated representative, for passage through the temporary safety zone. Passage through the safety zone will be evaluated on a case-by-case-basis to minimize impact and protect the general public, levee system, vessels and tows from destruction, loss or injury due to the hazards associated with rising flood water.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this 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 through the safety zone from May 26, 2011 through July 31, 2011. This safety zone is not expected to have a significant economic impact on a substantial number of small entities because vessels and tows may request permission and the necessary restrictions from the Captain of the Port Morgan City, or a designated

representative, for passage through the temporary safety zone.

If you are a small business entity and are significantly affected by this regulation, please contact LT Russell Pickering, Marine Safety Unit Morgan City, at (985) 380–5334.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

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.

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

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

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

Environment

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 is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule involves an emergency situation and will be in effect for over one week, but is not expected to result in any significant adverse environmental impact as described in NEPA.

An environmental analysis checklist and a categorical exclusion determination will be provided and made available at the docket as indicated in the **ADDRESSES** section.

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, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. A new temporary § 165.T08–0434 is added to read as follows:

§ 165.T08–0434 Safety Zone; Mile Marker 98.5 West of Harvey Lock Gulf Intracoastal Waterway to Mile Marker 108.5 West of Harvey Lock Gulf Intracoastal Waterway

(a) *Location.* Waters of the Gulf Intracoastal Waterway (GIWW) between West Harvey Lock Gulf West (WHL) MM 98.5 to MM 108.5.

(b) *Effective date.* This rule is effective May 26, 2011 through July 31, 2011 and enforceable with actual notice upon signature, May 26, 2011.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port Morgan City.

(2) Vessels requiring entry into or passage through the Safety Zone must request permission from the Captain of the Port Morgan City, or a designated representative. They may be contacted on VHF Channel 11, 13 or 16, or by telephone at (985) 380–5370.

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

Dated: May 26, 2011.

J.C. Burton,

Captain, U.S. Coast Guard, Captain of the Port Morgan City, Louisiana.

[FR Doc. 2011–15583 Filed 6–21–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0385]

RIN 1625–AA00

Safety Zone; Upper Mississippi River, Mile 180.0 to 179.0

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, from Mile 180.0 to 179.0, extending the entire width of the river. This safety zone is needed to protect persons, spectators, and vessels from safety hazards associated with a demonstration of Marine Corps combat capabilities. Entry into this zone is prohibited unless specifically authorized by the Captain of the Port Upper Mississippi River or a designated representative.

DATES: This rule is effective from 12 p.m. on June 23, 2011 through 6 p.m. CDT on June 25, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0385 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–0385 in the ''Keyword'' box, and then clicking ''Search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m. EST, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail Chief Petty Officer Bryan Klostermeyer, Sector Upper Mississippi River Response Department at telephone (314) 269–2566, e-mail *Bryan.K.Klostermeyer@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

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 using the NPRM process. The Coast Guard received minimal notice that the Marine Corps demonstration, which did not allow for the time needed to publish a NPRM and provide for a comment period. Delaying this rule by publishing a NPRM would be impracticable and unnecessarily delay the scheduled demonstration. This rule is needed to protect vessels and mariners from the safety hazards associated with such a demonstration.

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**. The Coast Guard received minimal notice that the Marine Corps demonstration, which did not allow for a 30-day notice period. Delaying this rule by providing 30 days notice would be impracticable and unnecessarily delay the scheduled demonstration. Delaying the rule's effective date would be impracticable because immediate action is needed to protect vessels and mariners from the safety hazards associated with a demonstration of Marine Corps combat capabilities.

Basis and Purpose

From June 23 through June 25, 2011 the USMC 3rd Battalion, 24th Marines will conduct a series of demonstrations of Marine Corps combat capabilities between Mile 180.0 and 179.0 on the Upper Mississippi River. This event presents safety hazards to the navigation of vessels between Mile 180.0 and 179.0, extending the entire width of the river. To provide for the safety of the public, the Coast Guard will temporarily restrict access to this section of the Upper Mississippi River during the scheduled demonstrations.

Discussion of Rule

The Coast Guard is establishing a temporary safety zone for all waters of the Upper Mississippi River, Mile 180.0 to 179.0, extending the entire width of the river. Entry into this zone is prohibited to all vessels and persons except participants and those persons and vessels specifically authorized by the Captain of the Port Upper Mississippi River. This rule is effective from 12 noon on June 23, 2011 through 6 p.m. CDT on June 25, 2011. This rule will be enforced from 3:30 p.m. until 5 p.m. CDT on June 23 and 24, 2011, and 1:30 p.m. until 3 p.m. CDT on June 25, 2011. The Captain of the Port Upper Mississippi River will inform the public through broadcast notice to mariners of all safety zone requirements changes and enforcement periods.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

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

Although this regulation will restrict access to this area, the effect of the rule is not significant because: (1) This rule will be in effect for a limited time period and notifications to the marine community will be made through local notice to mariners; and (2) vessels may be permitted to transit the area by the Captain of the Port Upper Mississippi River or designated representative.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this 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, Mile 180.0 to 179.0 after 12 noon on June 23, 2011 through 6 p.m. CDT on June 25, 2011. This safety zone will not have a significant economic impact on a substantial number of small entities because this rule will only be in effect for a limited period of time.

If you are a small business entity and are significantly affected by this regulation, please contact Chief Petty Officer Bryan Klostermeyer, Sector Upper Mississippi River at (314) 269–2566.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

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 businesses. 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.

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

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 is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule establishes a temporary safety zone to protect the public from the dangers associated with the scheduled demonstrations of Marine Corps combat capabilities. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping 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. 1226, 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; Department of Homeland Security Delegation No. 0170.1.

■ 2. A new temporary § 165.T11–0385 is added to read as follows:

§ 165.T11–0385 Safety Zone; Upper Mississippi River, Mile 180.0 to 179.0.

(a) *Location.* The following area is a safety zone: all waters of the Upper Mississippi River, Mile 180.0 to 179.0 extending the entire width of the waterway.

(b) *Effective date.* This rule is effective from 12 p.m. on June 23, 2011 through 6 p.m. CDT on June 25, 2011.

(c) *Periods of enforcement.* This rule will be enforced from 3:30 p.m. until 5 p.m. CDT on June 23 and 24, 2011, as well as, 1:30 p.m. until 3 p.m. CDT on June 25, 2011. The Captain of the Port Upper Mississippi River will inform the public of the enforcement periods and any safety zone changes through broadcast notice to mariners.

(d) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port Upper Mississippi River or a designated representative.

(2) Persons or vessels requiring entry into or passage through the zone must request permission from the Captain of the Port Upper Mississippi River or a designated representative. The Captain of the Port Upper Mississippi River representative may be contacted at (314) 269–2332.

(3) All persons and vessels shall comply with the instructions of the Captain of the Port Upper Mississippi River or their designated representative. Designated Captain of the Port representatives include United States Coast Guard commissioned, warrant, and petty officers.

Dated: May 25, 2011.

S.L. Hudson,

Captain, U.S. Coast Guard, Captain of the Port Upper Mississippi River.

[FR Doc. 2011–15621 Filed 6–21–11; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0432]

RIN 1625–AA00

Safety Zone; Waterway Closure, Morgan City-Port Allen Route From Mile Marker 0 to Port Allen Lock

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on specified waters of the Gulf Intracoastal Water Way, closing the Morgan City-Port Allen Route from MM 0 to the Port Allen lock to all commercial traffic. This temporary safety zone is needed to protect the general public, levee system, vessels and tows from destruction, loss or injury due to hazards associated with rising flood water.

DATES: Effective Date: this rule is effective in the CFR from June 22, 2011 until 11:59 p.m. July 31, 2011. This rule is effective with actual notice for purposes of enforcement beginning 12:01 a.m. May 16, 2011 through 11:59 p.m. July 31, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0432 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–0432 in the ''Keyword'' box, and then clicking ''Search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail Lieutenant (LT) Russell Pickering, Coast Guard; telephone 985–380–5334, e-mail *russell.t.pickering@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

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 publishing a NPRM would be impracticable since immediate action is needed to protect the general public, levee system, vessels and tows from the hazards associated with rising flood water on the Morgan City-Port Allen Route.

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**. Publishing a NPRM and delaying its effective date would be impracticable since immediate action is needed to protect the general public, levee system, vessels and tows from destruction, loss or injury due to the hazards associated with rising flood water on the Morgan City-Port Allen Route.

Basis and Purpose

Captains of the Port Morgan City and New Orleans, Louisiana have determined that there is a need to close certain waterways contingent on the predicted river heights and currents. This temporary safety zone is needed to protect the general public, levee system, vessels and tows from destruction, loss or injury from flood waters and associated hazards.

Discussion of Rule

The Coast Guard is establishing a temporary safety zone on the specified waters of the Gulf Intracoastal Water Way on the Morgan City–Port Allen Route from MM 0 to the Port Allen lock. Commercial vessels and tows may not enter this zone unless authorized by the Captains of the Port Morgan City or New Orleans.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that

Order. The Office of Management and Budget has not reviewed it under that Order.

Although this regulation will restrict access to the area, the effect of the rule will not be significant because notifications to the marine community will be made through broadcast notices to mariners and Local Notices to Mariners and Marine Safety Information Bulletins. Vessels requiring entry into or passage through the temporary safety zone may request permission from the Captains of the Port Morgan City or New Orleans, or a designated representative and entry will be evaluated on a case-by-case-basis to minimize impact and protect the general public, levee system, vessels and tows from destruction, loss or injury due to the hazards associated with rising flood water.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this 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 through the temporary safety zone from May 16, 2011 through July 31, 2011. This temporary safety zone is not expected to have a significant economic impact on a substantial number of small entities because vessels requiring entry into or passage through the temporary safety zone may request permission from the Captains of the Port Morgan City or New Orleans, or a designated representative.

If you are a small business entity and are significantly affected by this regulation, please contact LT Russell Pickering, Marine Safety Unit Morgan City, at (985) 380–5334.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

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.

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

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

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

Environment

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 is categorically excluded, under figure 2–1, paragraph (34) (g), of the Instruction. This rule involves an emergency situation and will be in effect for over one week, but is not expected to result in any significant adverse environmental impact as described in NEPA.

An environmental analysis checklist and a categorical exclusion determination will be provided and made available at the docket as indicated in the **ADDRESSES** section.

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; 50U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. A new temporary § 165.T08–0432 is added to read as follows:

§ 165.T08–0432 Safety Zone; Waterway Closure, Morgan City–Port Allen Route from Mile Marker 0 to Port Allen Lock.

(a) *Location.* Waters of the Gulf Intracoastal Water Way on the Morgan City—Port Allen route from MM 0 to the Port Allen lock.

(b) *Effective date.* This rule is effective May 16, 2011 through July 31, 2011.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captains of the Port Morgan City or New Orleans.

(2) Vessels requiring entry into or passage through the Safety Zone must request permission from the Captains of the Port Morgan City or New Orleans, or a designated representative. They may be contacted on VHF Channel 13 or 16, or by telephone at 985–380–5370.

(3) All persons and vessels shall comply with the instructions of the Captains of the Port Morgan City or New Orleans and designated on-scene patrol personnel. On-scene patrol personnel include commissioned, warrant, and petty officers of the U.S. Coast Guard.

Dated: May 16, 2011.

J.C. Burton,

Captain, U.S. Coast Guard, Captain of the Port Morgan City, Louisiana.

E.M. Stanton,

Captain, U.S. Coast Guard, Captain of the Port New Orleans, Louisiana.

[FR Doc. 2011–15588 Filed 6–21–11; 8:45 am]

BILLING CODE 9110–04–P

POSTAL SERVICE

39 CFR Part 952

Rules of Practice in Proceedings Relative to False Representation and Lottery Orders

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The Postal Service is adopting revised rules for proceedings relative to false representation and lottery orders. The primary purpose of this exercise is to update the rules and align them with current practices.

DATES: *Effective date:* July 22, 2011.

FOR FURTHER INFORMATION CONTACT: Diane M. Mego, Esq., 703–812–1905.

SUPPLEMENTARY INFORMATION: On March 15, 2011, the Postal Service published and requested comments concerning a proposed revision of 39 CFR part 952, concerning the rules of practice in proceedings relative to false representation and lottery orders (76 FR 13937–13944). The proposed rules of procedure were intended to have the same general coverage as the existing rules. The proposed new rules, however, were updated, were more comprehensive than the existing rules, and were intended to reflect more precisely current practice. No comments were received in response to this request.

Accordingly, the Postal Service has determined to adopt the revision of 39 CFR part 952 as proposed, with minor non-substantive changes in paragraphing and punctuation. The revised rules will completely replace the existing rules of practice, and in accordance with section 952.2 will apply to all formal proceedings before the Postal Service under 39 U.S.C. 3005, including such cases instituted under prior rules of practice.

List of Subjects in 39 CFR Part 952

Administrative practice and procedure, Fraud, False Representations, Lotteries, Penalties, Postal Service.

For the reasons stated in the preamble, the Postal Service revises 39 CFR part 952 to read as follows:

PART 952—RULES OF PRACTICE IN PROCEEDINGS RELATIVE TO FALSE REPRESENTATION AND LOTTERY ORDERS

Sec.

952.1 Authority.
952.2 Scope.
952.3 Informal dispositions.
952.4 Office business hours.
952.5 Complaints.
952.6 Interim impounding.
952.7 Notice of docketing and answer.
952.8 Service.
952.9 Filing documents for the record.
952.10 Answer.
952.11 Default.
952.12 Amendment of pleadings.
952.13 Continuances and extensions.
952.14 Hearings.
952.15 Change of place of hearings.
952.16 Appearances.
952.17 Presiding officers.
952.18 Evidence.
952.19 Subpoenas.
952.20 Witness fees.
952.21 Discovery.
952.22 Transcript.
952.23 Proposed findings and conclusions.
952.24 Decisions.
952.25 Exceptions to initial decision or tentative decision.
952.26 Judicial Officer.
952.27 Motion for reconsideration.
952.28 Orders.
952.29 Modification or revocation of orders.
952.30 Supplemental orders.
952.31 Computation of time.
952.32 Official record.
952.33 Public information.
952.34 Ex parte communications.

Authority: 39 U.S.C. 204, 401, 3005, 3012, 3016.

§ 952.1 Authority.

These rules of practice are issued by the Judicial Officer of the United States Postal Service (see § 952.26) pursuant to authority delegated by the Postmaster General, and in accordance with 39 U.S.C. 3005, and are governed by the Administrative Procedure Act, 5 U.S.C. 551, *et seq.*

§ 952.2 Scope.

These rules of practice shall be applicable in all formal proceedings before the Postal Service under 39 U.S.C. 3005, including such cases instituted under prior rules of practice pertaining to these or predecessor statutes, unless timely shown to be prejudicial to Respondent.

§ 952.3 Informal dispositions.

This part does not preclude the disposition of any matter by agreement between the parties either before or after

the filing of a complaint when time, the nature of the proceeding, and the public interest permit.

§ 952.4 Office business hours.

The offices of the officials identified in these rules are located at 2101 Wilson Boulevard, Suite 600, Arlington, VA 22201–3078, and are open Monday through Friday except holidays from 8:15 a.m. to 4:45 p.m.

§ 952.5 Complaints.

When the Chief Postal Inspector or his or her designated representative believes that a person is using the mails in a manner requiring formal administrative action under 39 U.S.C. 3005, he or she shall prepare and file with the Recorder a complaint which names the person involved; states the name, address and telephone number of the attorney representing Complainant; states the legal authority and jurisdiction under which the proceeding is initiated; states the facts in a manner sufficient to enable the person named therein to answer; and requests the issuance of an appropriate order or orders and/or the assessment of civil penalties. Complainant shall attach to the complaint a copy of the order or orders requested which may, at any time during the proceedings, be modified. The person named in the complaint shall be known as ''Respondent'', and the Chief Postal Inspector or his or her designee shall be known as ''Complainant''. The term ''person'' (1 U.S.C. 1) shall include any name, address, number or other designation under or by use of which Respondent seeks remittances of money or property through the mail.

§ 952.6 Interim impounding.

In preparation for or during the pendency of a proceeding initiated under 39 U.S.C. 3005, mail addressed to Respondent may be impounded upon obtaining an appropriate order from a United States District Court, as provided in 39 U.S.C. 3007.

§ 952.7 Notice of docketing and answer.

(a) Upon receipt of a complaint filed against a Respondent whose mailing address is within the United States, the Recorder shall issue a notice of docketing and answer due date stating the date for an answer which shall not exceed 30 days from the service of the complaint and a reference to the effect of failure to file an answer and/or the assessment of civil penalties authorized by 39 U.S.C. 3012. (See §§ 952.10 and 952.11).

(b) Upon receipt of a complaint filed against a Respondent whose mailing address is not within the United States, the Judicial Officer shall review the complaint and any supporting information and determine whether a prima facie showing has been made that Respondent is engaged in conduct warranting issuance of the orders authorized by 39 U.S.C. 3005(a). Where the Judicial Officer concludes that a prima facie showing has not been made the complaint shall be dismissed. Where the Judicial Officer concludes that a prima facie showing has been made, he or she shall issue a tentative decision and orders which:

(1) Set forth findings of fact and conclusions of law;

(2) Direct Respondent to cease and desist from engaging in conduct warranting the issuance of an order authorized by 39 U.S.C. 3005(a);

(3) Direct that postal money orders drawn to the order of Respondent not be paid for 45 days from date of the tentative decision;

(4) Direct that mail addressed to Respondent be forwarded to designated facilities and detained for 45 days from the date of the tentative decision subject to survey by Respondent and release of mail unrelated to the matter complained of;

(5) Tentatively assess such civil penalties as he considers appropriate under applicable law; and

(6) Provide that unless Respondent presents, within 45 days of the date of the tentative decision, good cause for dismissing the complaint, or modifying the tentative decision and orders, the tentative decision and orders shall become final.

(c) The Judicial Officer may, upon a showing of good cause made within 45 days of the date of the tentative decision, hold a hearing to determine whether the tentative decision and orders should be revoked, modified, or allowed to become final. Should a hearing be granted, the Judicial Officer may modify the tentative decision and orders to extend the time during which the payment of postal money orders payable to Respondent is suspended and mail addressed to Respondent is detained.

§ 952.8 Service.

(a) Where Respondent's mailing address is within the United States, the Recorder shall cause a notice of docketing and answer due date (the ''Notice''), a copy of these rules of practice, and a copy of the complaint to be transmitted to Complainant who shall serve those documents upon Respondent or his or her agent by certified mail, return receipt requested. Service shall be complete upon mailing. A receipt acknowledging delivery of the notice shall be secured from Respondent or his or her agent and forwarded to the Recorder, U.S. Postal Service, 2101 Wilson Boulevard, Suite 600, Arlington, VA 22201–3078, to become a part of the official record. In the absence of a receipt, Complainant shall file an Affidavit of Service, along with returned undelivered mail, or other appropriate evidence of service, with the Recorder. In the alternative Complainant may, in its discretion, effectuate service by hand on Respondent and file an Affidavit of Service with the Recorder.

(b) Where the only address against which Complainant seeks relief is outside the United States, a copy of the complaint, the tentative decision, and a copy of these rules of practice shall be sent by international mail, return receipt requested, by the Recorder to the address cited in the complaint. A written statement by the Recorder noting the time and place of mailing shall be accepted as evidence of service in the event a signed return receipt is not returned to the Recorder.

§ 952.9 Filing documents for the record.

(a) Each party shall file with the Recorder pleadings, motions, proposed orders, and other documents for the record. Discovery need not be filed except as may be sought to be included in the record, or as may be ordered by the presiding officer. Each filing after the initial complaint shall be served upon all other parties to the proceeding by the filing party, and an affidavit of such service signed and dated by the filing party shall be included on the last page of such filing, which shall state as follows:

> I, [name of filing party] hereby certify that I served the within [title of document] upon each party of record by electronic mail or first class mail on [date].

(b) The parties shall file one original of all documents filed under this section unless otherwise ordered by the presiding officer.

(c) Documents shall be dated and state the docket number and title of the proceeding. Any pleading or other document required by order of the presiding officer to be filed by a specified date must be received by the Recorder on or before such date. The date of filing shall be entered thereon by the Recorder.

(d) The presiding officer may permit filing of pleadings, motions, proposed orders, and other documents for the record by facsimile or by electronic mail with the Recorder.

§ 952.10 Answer.

(a) The answer shall contain a concise statement admitting, denying, or explaining each of the allegations set forth in the complaint.

(b) Any facts alleged in the complaint which are not denied or are expressly admitted in the answer may be considered as proved, and no further evidence regarding these facts need be adduced at the hearing.

(c) The answer shall be signed personally by an individual Respondent, or in the case of a partnership by one of the partners, or, in the case of a corporation or association, by an officer thereof.

(d) The answer shall set forth Respondent's address, electronic mail address, and telephone number or the name, address, electronic mail address, and telephone number of an attorney representing Respondent.

(e) The answer shall affirmatively state whether the Respondent will appear in person or by counsel at the hearing.

(f) In lieu of appearing at the hearing in person or by counsel, Respondent may request that the matter be submitted for determination pursuant to § 952.17(b)(10).

§ 952.11 Default.

(a) If Respondent fails to file an answer within the time specified in the notice of docketing and answer, Respondent may be deemed in default, and to have waived hearing and further procedural steps. The Judicial Officer may thereafter issue orders and/or assess civil penalties without further notice.

(b) If Respondent files an answer but fails to appear at the hearing, Respondent may, unless timely indications to the contrary are received, be deemed to have abandoned the intention to present a defense to the charges of the complaint, and the Judicial Officer, without further notice to Respondent, may issue the orders and/or assess civil penalties sought in the complaint.

(c) If Respondent or Complainant fails to respond to or comply with an order of the presiding officer, the party may be held in default, and absent good cause shown, the party may be deemed to have abandoned the intention to present a defense, or to prosecute the complaint, and the presiding officer or Judicial Officer, without further notice to the offending party, may, as appropriate, dismiss the complaint or issue the orders and/or assess civil penalties sought in the complaint.

§ 952.12 Amendment of pleadings.

(a) Amendments shall be filed with the Recorder.

(b) By consent of the parties, a pleading may be amended at any time. Also, a party may move to amend a pleading at any time prior to the close of the hearing and, provided that the amendment is reasonably within the scope of the proceeding initiated by the complaint, the presiding officer rule on the motion as he or she deems to be fair and equitable to the parties.

(c) When issues not raised by the pleadings but reasonably within the scope of the proceedings initiated by the complaint are tried by express or implied consent of the parties, they shall be treated in all respects as if they had been raised in the pleadings. Such amendments as may be necessary to conform the pleadings to the evidence and to raise such issues may be allowed at any time upon the motion of any party.

(d) If a party objects to the introduction of evidence at the hearing on the ground that it is not within the issues raised by the pleadings, but fails to satisfy the presiding officer that an amendment of the pleadings would prejudice him or her on the merits, the presiding officer may allow the pleadings to be amended and may grant a continuance to enable the objecting party to rebut the evidence presented.

(e) The presiding officer may, upon reasonable notice and upon such terms as are just, permit service of a supplemental pleading setting forth transactions, occurrences, or events which have occurred since the date of the pleading sought to be supplemented and which are relevant to any of the issues involved.

§ 952.13 Continuances and extensions.

Continuances and extensions will not be granted by the presiding officer except for good cause shown.

§ 952.14 Hearings.

Hearings are held at 2101 Wilson Boulevard, Suite 600, Arlington, VA 22201–3078, or other locations designated by the presiding officer. Time, date, and location for the hearing shall be set by the presiding officer in his or her sole discretion.

§ 952.15 Change of place of hearings.

(a) A party may file a request that a hearing be held to receive evidence in his or her behalf at a place other than that designated in § 952.14. The party shall support the request with a statement outlining:

(1) The evidence to be offered in such place;

(2) The names and addresses of the witnesses who will testify; and,

(3) The reasons why such evidence cannot be produced at Arlington, VA.

(b) The presiding officer shall give consideration to the convenience and necessity of the parties and witnesses and the relevance of the evidence to be offered.

§ 952.16 Appearances.

(a) Respondent may appear and be heard in person or by attorney. A Notice of Appearance must be filed by any attorney representing Respondent.

(b) An attorney may practice before the Postal Service in accordance with applicable rules issued by the Judicial Officer. See 39 CFR Part 951.

(c) When Respondent is represented by an attorney, all pleadings and other papers subsequent to the complaint shall be mailed to the attorney.

(d) Withdrawal by any attorney representing a party must be preceded by a motion to withdraw stating the reasons therefore, and shall be granted in the discretion of the presiding officer. If a successor attorney is not appointed at the same time, withdrawing counsel shall provide adequate contact information for Respondent.

(e) Parties must promptly file a notice of change of attorney.

§ 952.17 Presiding officers.

(a) The presiding officer at any hearing shall be an Administrative Law Judge qualified in accordance with law or the Judicial Officer (39 U.S.C. 204). The Chief Administrative Law Judge shall assign cases. The Judicial Officer may, for good cause shown, preside at the hearing if an Administrative Law Judge is unavailable.

(b) The presiding officer shall have authority to:

(1) Administer oaths and affirmations;

(2) Examine witnesses;

(3) Rule upon offers of proof, admissibility of evidence, and matters of procedure;

(4) Order any pleading amended upon motion of a party at any time prior to the close of the hearing;

(5) Maintain discipline and decorum and exclude from the hearing any person acting in an inappropriate manner;

(6) Require the filing of briefs or memoranda of law on any matter upon which he or she is required to rule;

(7) Order prehearing conferences for the purpose of the settlement or simplification of issues by the parties;

(8) Order the proceeding reopened at any time prior to his or her decision for the receipt of additional evidence;

(9) Render an initial decision, which becomes the final agency decision

unless a timely appeal is taken, except that the Judicial Officer may issue a tentative or a final decision;

(10) Rule on motion by either party, or on his or her own initiative, for a determination on the written record in lieu of an oral hearing in his or her sole discretion;

(11) Rule on motion by either party, or on his or her own initiative, to permit a hearing to be conducted by telephone, video conference, or other appropriate means;

(12) Rule upon applications and requests filed under §§ 952.19 and 952.21; and

(13) Exercise all other authority conferred upon the presiding officer by the Administrative Procedure Act or other applicable law.

§ 952.18 Evidence.

(a) Except as otherwise provided in these rules, the Federal Rules of Evidence shall govern. However, such rules may be relaxed to the extent that the presiding officer deems proper to ensure a fair hearing. The presiding officer may exclude irrelevant, immaterial, or repetitious evidence.

(b) Testimony shall be under oath or affirmation and witnesses shall be subject to cross-examination.

(c) Agreed statements of fact may be received in evidence.

(d) Official notice, judicial notice or administrative notice of appropriate information may be taken in the discretion of the presiding officer.

(e) Authoritative writings of the medical or other sciences may be admitted in evidence, but only through the testimony of expert witnesses or by stipulation.

(f) Lay testimonials may be received in evidence as proof of the efficacy or quality of any product, service, or thing sold through the mails, in the discretion of the presiding officer.

(g) The written statement of a competent witness may be received in evidence provided that such statement is relevant to the issues, that the witness shall testify under oath at the hearing that the statement is in all respects true, and, in the case of expert witnesses, that the statement correctly states the witness's opinion or knowledge concerning the matters in question.

(h) A party which objects to the admission of evidence shall explain the grounds for the objection. Formal exceptions to the rulings of the presiding officer are unnecessary.

§ 952.19 Subpoenas.

(a) *General.* Upon written request of either party filed with the Recorder or on his or her own initiative, the presiding officer may issue a subpoena requiring:

(1) *Testimony at a deposition.* The deposing of a witness in the city or county where the witness resides or is employed or transacts business in person, or at another location convenient for the witness that is specifically determined by the presiding officer;

(2) *Testimony at a hearing.* The attendance of a witness for the purpose of taking testimony at a hearing; and

(3) *Production of records.* The production by the witness at a deposition or hearing of records designated in the subpoena.

(b) *Voluntary cooperation.* Each party is expected:

(1) To cooperate and make available witnesses and evidence under its possession, custody or control as requested by the other party, without issuance of a subpoena, and

(2) To secure voluntary production of desired third-party records whenever possible.

(c) *Requests for subpoenas.* (1) A request for a subpoena shall to the extent practical be filed:

(i) At the same time a request for deposition is filed; or

(ii) Fifteen (15) days before a scheduled hearing where the attendance of a witness at a hearing is sought.

(2) A request for a subpoena shall state the reasonable scope and relevance to the case of the testimony and of any records sought.

(3) The presiding officer, in his or her sole discretion, may honor requests for subpoenas not presented within the time limitations specified in this paragraph.

(d) *Motion to quash or modify.* (1) Upon written request by the person subpoenaed or by a party, the presiding officer may:

(i) Quash or modify the subpoena if it is unreasonable, oppressive or for other good cause shown, or

(ii) Require the person in whose behalf the subpoena was issued to advance the reasonable cost of producing subpoenaed records. Where circumstances require, the presiding officer may act upon such a request at any time after a copy has been served upon the opposing party.

(2) Motions to quash or modify a subpoena shall be filed within 10 days of service, or at least one day prior to any scheduled hearing, whichever first occurs. The presiding officer, in his or her sole discretion, may entertain motions to quash or modify not made within the time limitations specified in this paragraph.

(e) *Form; issuance.* (1) Every subpoena shall state the title of the proceeding, shall cite 39 U.S.C. 3016(a)(2) as the authority under which it is issued, and shall command each person to whom it is directed to attend and give testimony, and if appropriate, to produce specified records at a time and place therein specified. In issuing a subpoena to a requesting party, the presiding officer shall sign the subpoena and may, in his or her discretion, enter the name of the witness and otherwise leave it blank. The party to whom the subpoena is issued shall complete the subpoena before service.

(2) The party at whose instance a subpoena is issued shall be responsible for the payment of fees and mileage of the witness in accordance with 28 U.S.C. 1821, or other applicable law, and of the officer who serves the subpoena. The failure to make payment of such charges on demand may be deemed by the presiding officer as sufficient ground for striking the testimony of the witness and the evidence the witness has produced.

(f)(1) *Service in general.* The party requesting issuance of a subpoena shall arrange for service.

(2) *Service within the United States.* A subpoena issued under this section may be served by a person designated under 18 U.S.C. 3061 or by a United States marshal or deputy marshal, or by any other person who is not a party and not less than 18 years of age at any place within the territorial jurisdiction of any court of the United States.

(3) *Service outside the United States.* Any such subpoena may be served upon any person who is not to be found within the territorial jurisdiction of any court of the United States, in such manner as the Federal Rules of Civil Procedure prescribe for service in a foreign country. To the extent that the courts of the United States may assert jurisdiction over such person consistent with due process, the United States District Court for the District of Columbia shall have the same jurisdiction to take any action respecting compliance with this section by such person that such court would have if such person were personally within the jurisdiction of such court.

(4) *Service on business persons.* Service of any such subpoena may be made upon a partnership, corporation, association, or other legal entity by:

(i) Delivering a duly executed copy thereof to any partner, executive officer, managing agent, or general agent thereof, or to any agent thereof authorized by appointment or by law to receive service of process on behalf of such partnership, corporation, association, or entity;

(ii) Delivering a duly executed copy thereof to the principal office or place of business of the partnership, corporation, association, or entity; or

(iii) Depositing such copy in the United States mails, by registered or certified mail, return receipt requested, duly addressed to such partnership, corporation, association, or entity at its principal office or place of business.

(5) *Service on natural persons.* Service of any subpoena may be made upon any natural person by:

(i) Delivering a duly executed copy to the person to be served; or

(ii) Depositing such copy in the United States mails, by registered or certified mail, return receipt requested, duly addressed to such person at his or her residence or principal office or place of business.

(6) *Verified return.* A verified return by the individual serving any such subpoena setting forth the manner of such service shall constitute proof of service. In the case of service by registered or certified mail, such return shall be accompanied by the return post office receipt of delivery of such subpoena, or a statement of service by registered or certified mail in the event that receipt of delivery is unavailable.

(g) *Contumacy or refusal to obey a subpoena.* In the case of refusal to obey a subpoena, the Judicial Officer may request the Attorney General to petition the district court for any district in which the person receiving the subpoena resides, is found, or conducts business (or in the case of a person outside the territorial jurisdiction of any district court, the district court for the District of Columbia) to issue an appropriate order for the enforcement of such subpoena. Any failure to obey such order of the court may be punishable as contempt.

§ 952.20 Witness fees.

The Postal Service does not pay fees and expenses for Respondent's witnesses or for depositions requested by Respondent, unless otherwise ordered by the presiding officer.

§ 952.21 Discovery.

(a) *Voluntary discovery.* The parties are encouraged to engage in voluntary discovery procedures. In connection with any deposition or other discovery procedure, the presiding officer may issue any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, and those orders may include limitations on the scope, method, time and place for discovery, and provisions for protecting the secrecy of confidential information or documents.

(b) *Discovery disputes.* The parties are required to make a good faith effort to resolve objections to discovery requests informally. A party receiving an objection to a discovery request, or a party which believes that another party's response to a discovery request is incomplete or entirely absent, may file a motion to compel a response, but such a motion must include a representation that the moving party has tried in good faith, prior to filing the motion, to resolve the matter informally. The motion to compel shall include a copy of each discovery request at issue and the response, if any.

(c) *Discovery limitations.* The presiding officer may limit the frequency or extent of use of discovery methods described in these rules. In doing so, generally the presiding officer will consider whether:

(1) The discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive;

(2) The party seeking discovery has had ample opportunity by discovery in the case to obtain the information sought; or

(3) The discovery is unduly burdensome and expensive, taking into account the needs of the case, the amount in controversy, limitations on the parties' resources, and the importance of the issues at stake.

(d) *Interrogatories.* At any time after service of the complaint, a party may serve on the other party written interrogatories to be answered separately in writing, signed under oath and returned within 30 days. Upon timely objection, the presiding officer will determine the extent to which the interrogatories will be permitted.

(e) *Requests for admission.* At any time after service of the complaint, a party may serve upon the other party a request for the admission of specified facts. Within 30 days after service, the party served shall answer each requested fact or file objections thereto. The factual propositions set out in the request may be ordered by the presiding officer as deemed admitted upon the failure of a party to respond timely and fully to the request for admissions.

(f) *Requests for production of documents.* At any time after service of the complaint, a party may serve on the other party written requests for the production, inspection, and copying of any documents, electronically stored information, or things, to be answered within 30 days. Upon timely objection, the presiding officer will determine the extent to which the requests must be satisfied, and if the parties cannot themselves agree thereon, the presiding officer shall specify just terms and conditions for compliance.

(g) *Depositions.* Except as stated herein, depositions shall be conducted in accordance with Rule 30 of the Federal Rules of Civil Procedure.

(1) After a complaint has been filed and docketed, the parties may mutually agree to, or the presiding officer may, upon application of either party and for good cause shown, order the taking of testimony of any person by deposition upon oral examination or written interrogatories before any officer authorized to administer oaths at the place of examination, for use as evidence or for purpose of discovery. The application for order shall specify whether the purpose of the deposition is discovery or for use as evidence.

(2) The time, place, and manner of conducting depositions shall be as mutually agreed by the parties or, failing such agreement, and upon proper application, governed by order of the presiding officer.

(3) No testimony taken by deposition shall be considered as part of the evidence in the hearing of an appeal unless and until such testimony is offered and received in evidence at or before such hearing. It will not ordinarily be received in evidence if the deponent is available to testify at the hearing, but the presiding officer may admit testimony taken by deposition in his or her discretion. A deposition may be used to contradict or impeach the testimony of the witness given at the hearing. In cases submitted on the written record in lieu of an oral hearing, the presiding officer may, in his or her discretion, receive depositions as evidence in supplementation of that record.

(4) Each party shall bear its own expenses associated with the taking of any deposition unless otherwise ordered by the presiding officer.

(h) *Sanctions.* If a party fails to appear for a deposition, after being served with a proper notice, or fails to serve answers or objections to interrogatories, requests for admissions, or requests for the production or inspection of documents, after proper service, the party seeking discovery may request that the presiding officer impose appropriate orders. Failure of a party to comply with an order pursuant to this rule may result in the presiding officer's ruling that the disobedient party may not support or oppose designated charges or defenses or may not introduce designated matters in evidence. The presiding officer may also infer from the disobedient party's

failure to comply with the order that the facts to which the order related would, if produced or admitted, be adverse to such party's interests. In the sole discretion of the presiding officer, failure of a party to comply with an order pursuant to this rule may result in the presiding officer's issuance of an order of default under § 952.11(c).

§ 952.22 Transcript.

(a) Hearings shall be reported and transcribed by a court reporter. Argument upon any matter may be excluded from the transcript by order of the presiding officer. A copy of the transcript shall be a part of the record and the sole official transcript of the proceeding. Copies of the transcript shall be supplied to the parties to the proceeding by the reporter at rates not to exceed the maximum rates fixed by contract between the Postal Service and the reporter. Copies of parts of the official record including exhibits admitted into evidence, other than the transcript, may be obtained by Respondent from the Recorder upon the payment of reasonable copying charges. Items that cannot reasonably be photocopied may be photographed and furnished in that form.

(b) Changes in the official transcript may be ordered by the presiding officer only to correct errors affecting substance and then only in the manner herein provided. Within 10 days after the receipt by any party of a copy of the official transcript, or any part thereof, he or she may file a motion requesting correction of the transcript. Opposing counsel shall, within such time as may be specified by the presiding officer, notify the presiding officer in writing of his or her concurrence or disagreement with the requested corrections. Failure to interpose timely objection to a proposed correction shall be considered to be concurrence. Thereafter, the presiding officer shall by order specify the corrections to be made in the transcript. The presiding officer on his or her own initiative may order corrections to be made in the transcript with prompt notice to the parties of the proceeding. Any changes ordered by the presiding officer other than by agreement of the parties shall be subject to objection and exception.

§ 952.23 Proposed findings and conclusions.

(a) Each party to a proceeding, except one who fails to answer the complaint or, having answered, either fails to appear at the hearing or indicates in the answer that he or she does not desire to appear, may, unless at the discretion of the presiding officer such is not appropriate, submit proposed findings of fact, conclusions of law, orders and supporting reasons either in oral or written form in the discretion of the presiding officer. The presiding officer may also require parties to any proceeding to submit proposed findings of fact, conclusions of law, orders, and supporting reasons. Unless given orally, the date set for filing of proposed findings of fact, conclusions of law, orders and supporting reasons shall be within 30 days after the delivery of the official transcript to the Recorder who shall notify both parties of the date of its receipt. The filing date for proposed findings of fact, conclusions of law, orders and supporting reasons shall be the same for both parties. If not submitted by such date, or unless extension of time for the filing thereof is granted, they will not be included in the record or given consideration.

(b) Except when presented orally before the close of the hearing, proposed findings of fact shall be set forth in serially numbered paragraphs and shall state with particularity all evidentiary facts in the record with appropriate citations to the transcript or exhibits supporting the proposed findings. Each proposed conclusion shall be separately stated.

(c) Except when presented orally before the close of the hearing, proposed orders shall state the statutory basis of the order and, with respect to orders proposed to be issued pursuant to 39 U.S.C. 3005(a)(3), shall be set forth in serially numbered paragraphs stating with particularity the representations Respondent and its representative shall cease and desist from using for the purpose of obtaining money or property through the mail.

§ 952.24 Decisions.

(a) *Initial decision by Administrative Law Judge.* A written initial decision shall be rendered by an Administrative Law Judge as soon as practical after completion of the hearing, or after close of the record in matters heard upon the written record in lieu of an oral hearing under § 952.17(b)(10). The initial decision shall include findings and conclusions with the reasons therefor upon all the material issues of fact or law presented on the record, and the appropriate orders or denial thereof. The initial decision shall become the final agency decision unless an appeal is taken in accordance with § 952.25.

(b) *Tentative or final decision by the Judicial Officer.* When the Judicial Officer presides at the hearing he or she shall issue a final or a tentative decision. Such decision shall include findings and conclusions with the reasons therefor upon all the material issues of fact or law presented on the record, and the appropriate orders or denial thereof. The tentative decision shall become the final agency decision unless exceptions are filed in accordance with § 952.25.

(c) *Oral decisions.* The presiding officer may render an oral decision (an initial decision by an Administrative Law Judge, or a tentative or final decision by the Judicial Officer) at the close of the hearing when the nature of the case and the public interest warrant. A party which desires an oral decision shall notify the presiding officer and the opposing party at least 5 days prior to the date set for the hearing. Either party may submit proposed findings, conclusions, and proposed orders either orally or in writing at the conclusion of the hearing.

§ 952.25 Exceptions to initial decision or tentative decision.

(a) A party in a proceeding presided over by an Administrative Law Judge may appeal to the Judicial Officer by filing exceptions in a brief on appeal within 15 days from the receipt of the Administrative Law Judge's initial decision.

(b) A party in a proceeding presided over by the Judicial Officer may file exceptions within 15 days from the receipt of the Judicial Officer's tentative decision.

(c) If an initial or tentative decision is rendered orally by the presiding officer at the close of the hearing, he or she may then orally provide notice to the parties participating in the hearing of the time limit within which an appeal must be filed.

(d) The date for filing the reply to an appeal brief or to a brief in support of exceptions to a tentative decision by the Judicial Officer is 10 days after the receipt thereof. No additional briefs shall be received unless requested by the Judicial Officer.

(e) Briefs upon appeal or in support of exceptions to a tentative decision by the Judicial Officer and replies thereto shall be filed in duplicate with the Recorder and contain the following matter:

(1) A subject index of the matters presented, with page references; a table of cases alphabetically arranged; a list of statutes and texts cited with page references;

(2) A concise abstract or statement of the case in briefs on appeal or in support of exceptions;

(3) Numbered exceptions to specific findings and conclusions of fact, conclusions of law, or recommended orders of the presiding officer in briefs

on appeal or in support of exceptions; and

(4) A concise argument clearly setting forth points of fact and of law relied upon in support of or in opposition to each exception taken, together with specific references to the parts of the record and the legal or other authorities relied upon.

(f) Unless permission is granted by the Judicial Officer no brief shall exceed 50 printed pages double spaced, using 12 point type.

(g) The Judicial Officer will extend the time to file briefs only upon written application for good cause shown. If the appeal brief or brief in support of exceptions is not filed within the time prescribed, the defaulting party may be deemed to have abandoned the appeal or waived the exceptions, and the initial or tentative decision shall become the final agency decision.

§ 952.26 Judicial Officer.

(a) The Judicial Officer is authorized:

(1) To act as presiding officer;

(2) To render tentative decisions;

(3) To render final agency decisions;

(4) To issue Postal Service orders for the Postmaster General;

(5) To refer the record in any proceeding to the Postmaster General or the Deputy Postmaster General for final agency decision;

(6) To remand a case to the presiding officer for consideration; and,

(7) To revise or amend these rules of practice.

(b) In determining appeals from initial decisions or exceptions to tentative decisions, the entire official record will be considered before a final agency decision is rendered. Before rendering a final agency decision, the Judicial Officer may order the hearing reopened for the presentation of additional evidence by the parties.

§ 952.27 Motion for reconsideration.

A party may file a motion for reconsideration of a final agency decision within 10 days after receiving it or within such longer period as the Judicial Officer may order. Each motion for reconsideration shall be accompanied by a brief clearly setting forth the points of fact and of law relied upon in support of said motion.

§ 952.28 Orders.

(a) If an order is issued which prohibits delivery of mail to Respondent it shall be incorporated in the record of the proceeding. The Recorder shall cause notice of the order to be published in the Postal Bulletin and cause the order to be transmitted to such postmasters and other officers and employees of the Postal Service as may be required to place the order into effect.

(b) If an order is issued which requires Respondent to cease and desist from using certain representations for the purpose of obtaining money or property through the mail, it shall be incorporated in the record of the proceeding and a copy thereof shall be served upon Respondent or his or her or its agent by certified mail or by personal service, or if no person can be found to accept service, service shall be accomplished by ordinary mail to the last known address of Respondent or his or her or its agent. If service is not accomplished by certified mail, a statement, showing the time and place of delivery, signed by the postal employee who delivered the order, shall be forwarded to the Recorder.

§ 952.29 Modification or revocation of orders.

A party against which an order or orders have been issued may file an application for modification or revocation thereof. The Recorder shall transmit a copy of the application to the Chief Postal Inspector or his or her designee, who shall file a written reply within 10 days after filing or such other period as the Judicial Officer may order. A copy of the reply shall be sent to the applicant by the Recorder. Thereafter an order granting or denying such application will be issued by the Judicial Officer.

§ 952.30 Supplemental orders.

When the Chief Postal Inspector or his or her designee, or the Chief Postal Inspector's designated representative shall have reason to believe that a person is evading or attempting to evade the provisions of any such orders by conducting the same or a similar enterprise under a different name or at a different address, he or she may file a petition with accompanying evidence setting forth the alleged evasion or attempted evasion and requesting the issuance of a supplemental order or orders against the name or names allegedly used. Notice shall then be given by the Recorder to the person that the order has been requested and that an answer may be filed within 10 days of the notice. The Judicial Officer, for good cause shown, may hold a hearing to consider the issues in controversy, and shall, in any event, render a final decision granting or denying the supplemental order or orders.

§ 952.31 Computation of time.

A designated period of time under these rules excludes the day the period begins, and includes the last day of the period unless the last day is a Saturday, Sunday, or legal holiday, in which event the period runs until the close of business on the next business day.

§ 952.32 Official record.

The hearing transcript together with all pleadings, orders, exhibits, briefs and other documents filed in the proceeding shall constitute the official record of the proceeding.

§ 952.33 Public information.

The Librarian of the Postal Service maintains for public inspection in the Library copies of all initial, tentative and final agency decisions and orders. The Recorder maintains the complete official record of every proceeding.

§ 952.34 Ex parte communications.

The provisions of 5 U.S.C. 551(14), 556(d), and 557(d) prohibiting ex parte communications apply to proceedings under these rules of practice.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 2011–15518 Filed 6–21–11; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2011–0411; FRL–9321–5]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Adoption of the Revised Nitrogen Dioxide Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the Commonwealth of Virginia State Implementation Plan (SIP). The revisions add the new 1-hour nitrogen dioxide (NO_2) standard at a level of 100 parts per billion (ppb) and update the list of Federal documents incorporated by reference. The Commonwealth of Virginia's SIP revisions for the national ambient air quality standards (NAAQS) for NO_2 are consistent with the Federal NO_2 standards. This action is being taken under the Clean Air Act (CAA).

DATES: This rule is effective on August 22, 2011 without further notice, unless EPA receives adverse written comment by July 22, 2011. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2011–0411 by one of the following methods:

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

B. *E-mail: fernandez.cristina@epa.gov.*

C. *Mail:* EPA–R03–OAR–2011–0411, Cristina Fernandez, Associate Director, Office of Air Program Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2011–0411. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an anonymous access system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Gregory Becoat, (215) 814–2036, or by e-mail at *becoat.gregory@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 4, 2011, the Commonwealth of Virginia submitted a formal revision to its SIP. The SIP revision consists of amendments pertaining to the ambient air quality standards for NO_2 and related reference conditions. The CAA specifies that EPA must re-evaluate the appropriateness of its various air quality standards every five years. As part of the process, EPA reviewed the latest research and determined that revised standards for NO_2 were necessary to protect public health. EPA revised the level of the primary standard by setting a new 1-hour NO_2 standard at a level of 100 parts per billion (ppb) in order to protect against adverse health effects associated with short-term exposure to NO_2. EPA also retained the current annual average NO_2 standard of 53 ppb in order to protect against adverse health effects associated with long-term exposure to NO_2. EPA promulgated the more stringent primary NAAQS for NO_2 on February 9, 2010 (75 FR 6474).

II. Summary of SIP Revision

On March 4, 2011, the Commonwealth of Virginia submitted a formal revision to its SIP. The SIP revision consists of amendments to the Commonwealth's existing regulations in order to update the list of appendices under documents incorporated by reference and to add the new primary 1-hour standard for NO_2. The Commonwealth of Virginia's revision incorporates the revised NO_2 standard into the Code of Virginia (9VAC5 Chapter 30). This SIP revision amends regulation 5–30–70, ''Oxides of nitrogen with nitrogen dioxide as the indicator'' in order to specify that NO_2 is the indicator for oxides of nitrogen; limit the 53 ppb standard to the annual primary standard and change the unit of measurement from annual arithmetic mean concentration to annual average concentration; add the new primary 1-hour standard of 100 ppb; specify reference methods used to measure the standard; and specify how the primary annual and 1-hour standard and the secondary standard are attained.

In addition, this SIP revision amends regulation 5–20–21, ''Documents incorporated by reference'' by adding the new Appendix S to the list of Federal documents incorporated by reference. Appendix S was added to 40 CFR part 50 when the revised NO_2 standard was promulgated on February 9, 2010 (75 FR 6474).

III. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) ''privilege'' for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginias Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information (1) that are generated or developed before the commencement of a voluntary environmental assessment; (2) that are prepared independently of the assessment process; (3) that demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) that are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege Law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information ''required by law,'' including documents and information ''required by Federal law to

maintain program delegation, authorization or approval,'' since Virginia must ''enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts. * * *'' The opinion concludes that ''[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval.''

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that ''[t]o the extent consistent with requirements imposed by Federal law,'' any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since ''no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity.''

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, EPA may at any time invoke its authority under the CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the CAA is likewise unaffected by this, or any, state audit privilege or immunity law.

IV. Final Action

EPA is approving the Commonwealth of Virginia's SIP revision that adds the new 1-hour NO_2 NAAQS and updates the list of Federal documents incorporated by reference. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comment. However, in the Proposed Rules section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective on August 22, 2011 without further notice unless EPA receives adverse comment by July 22, 2011. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

V. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA 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'' 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 (Pub. L. 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.

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this 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).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 22, 2011. 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. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action

pertaining to the Commonwealth of Virginia's adoption of the revised NO_2 standard of 100 ppb may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Reporting and recordkeeping requirements.

Dated: June 6, 2011.

W.C. Early,

Acting, Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for 40 CFR part 52 continues to read as follows:

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

Subpart VV—Virginia

■ 2. In § 52.2420, the table in paragraph (c) is amended by revising the entry for Section 5–30–70. The table in paragraph (e) is amended by adding an entry for ''Documents Incorporated by Reference'' after the tenth existing entry for ''Documents Incorporated by Reference.'' The amendments read as follows:

§ 52.2420 Identification of plan.

* * * * *

(c) * * *

EPA—APPROVED VIRGINIA REGULATIONS AND STATUTES

State citation	Title/subject	State effective date	EPA approval date	Explanation [former SIP citation]
* *	*	*	* *	*
9 VAC 5, Chapter 30 Ambient Air Quality Standards [Part III]				
* *	*	*	* *	*
5-30-70	Oxides of nitrogen dioxide as the indicator.	8/18/10	6/22/11 [Insert page number where the document begins].	Sections A., D., and E. are modified. Sections B., C., F., and G. are added.
* *	*	*	* *	*

* * * * *

(e) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
* *	*	*	* *	*
Documents Incorporated by Reference (9 VAC 5-20-21, Section E.1.a.(1)(s)).	Statewide	3/14/11	6/22/11 [Insert page number where the document begins].	Added section.
* *	*	*	* *	*

[FR Doc. 2011–15455 Filed 6–21–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2010–1072; FRL–9321–4]

Approval and Promulgation of Implementation Plans; State of Idaho; Regional Haze State Implementation Plan and Interstate Transport Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving portions of a State Implementation Plan (SIP) revision submitted by the State of Idaho on October 25, 2010, as meeting the requirements of Clean Air Act (CAA) section 110(a)(2)(D)(i)(II) as it applies to visibility for the 1997 8-hour ozone and 1997 particulate matter ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS). EPA is also approving portions of the revision as meeting certain requirements of the regional haze program, including the requirements for best available retrofit technology (BART).

DATES: *Effective Date:* This final rule is effective July 22, 2011.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2010–1072. 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, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the State and Tribal Air Programs Unit, Office of Air Waste and Toxics, EPA Region 10, 1200 Sixth Avenue, Seattle, WA, 98101. 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 a.m. to 4 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Steve Body, EPA Region 10, Suite 900, Office of Air, Waste and Toxics, 1200 Sixth Avenue, Seattle, WA 98101.

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, CAA,* or *Clean Air Act* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The initials *SIP* mean or refer to State Implementation Plan.

(iv) The words *Idaho* and *State* mean the State of Idaho.

Table of Contents

I. Background Information
II. Response to Comments
III. Final Action
IV. Scope of Action
V. Statutory and Executive Orders Review

I. Background Information

On July 18, 1997, EPA promulgated new NAAQS for 8-hour ozone and for fine particulate matter ($PM_{2.5}$). This action is being taken, in part, in response to the promulgation of the 1997 8-hour ozone and $PM_{2.5}$ NAAQS. Section 110(a)(1) of the CAA requires states to submit a SIP revision to address a new or revised NAAQS within 3 years after promulgation of such standards, or within such shorter period as EPA may prescribe. Section 110(a)(2) lists the elements that such new SIPs must address, as applicable, including section 110(a)(2)(D)(i), which pertains to interstate transport of certain emissions.

Section 110(a)(2)(D)(i) of the CAA requires that a SIP must contain adequate provisions prohibiting any source or other type of emissions activity within the state from emitting any air pollutant in amounts which will: (1) contribute significantly to nonattainment of the NAAQS in any other state; (2) interfere with maintenance of the NAAQS by any other state; (3) interfere with any other state's required measures to prevent significant deterioration of air quality; or (4) interfere with any other state's required measures to protect visibility. This action addresses the fourth prong, section 110(a)(2)(D)(i)(II).

In the CAA Amendments of 1977, Congress established a program to protect and improve visibility in the national parks and wilderness areas. See CAA section 169(A). Congress amended the visibility provisions in the CAA in 1990 to focus attention on the problem of regional haze. See CAA section 169(B). EPA promulgated regulations in 1999 to implement sections 169A and 169B of the Act. These regulations require states to develop and implement plans to ensure reasonable progress toward improving visibility in mandatory Class I Federal areas[1] (Class I areas). 64 FR 35714 (July 1, 1999); see also 70 FR 39104 (July 6, 2005) and 71 FR 60612 (October 13, 2006).

On October 25, 2010, the State of Idaho submitted to EPA a State Implementation Plan (SIP) revision addressing the interstate transport requirements for visibility for the 1997 ozone and $PM_{2.5}$ NAAQS, [see CAA § 110(a)(2)(D)(i)(II)], and the requirements of the regional haze program at 40 CFR § 51.308 (Regional Haze SIP submittal). On January 11, 2011, EPA published a notice in which the Agency proposed to approve the Idaho SIP revision as meeting the requirements of both section 110(a)(2)(D)(i)(II) of the CAA and the Regional Haze requirements set forth in sections 169A and 169B of the CAA and in 40 CFR 51.300–308, with the exception of Chapter 11, Idaho Reasonable Progress Goal Demonstration and Chapter 12, Long Term Strategy. 76 FR 1579 (Notice of Proposed Rulemaking or NPR). For Idaho's Reasonable Progress Goal Determination and Long-Term Strategy, EPA did not propose taking any action.

II. Response to Comments

EPA received four comments on the proposed action to approve certain elements of the Idaho Regional Haze SIP submittal. A comment letter was received from the State of Idaho's Department of Environmental Quality (IDEQ). A comment was received from a private citizen. Adverse comments were received by two entities; The Amalgamated Sugar Company (TASCO) and the Wyoming Outdoor Council. The discussion below summarizes and responds to the comments received on EPA's proposed SIP action and explains the basis for EPA's final action.

Comment from IDEQ

Comment: IDEQ's letter related to a Tier II operating permit IDEQ had issued to The Amalgamated Sugar Company (TASCO) on September 7, 2010, that included the requirement to install and operate BART control technology and comply with the BART emission limitations. See the September 7, 2010, letter from IDEQ to TASCO issuing the Tier II Operating Permit No. T2–2009–0105, that was included in the Idaho Regional Haze SIP submittal. The comment explained that on October 12, 2011, TASCO appealed the Tier II permit and that IDEQ has entered into negotiations with TASCO to discuss alternative control measures that may be required at the TASCO Nampa facility in lieu of the BART conditions as outlined in the SIP submission. IDEQ and TASCO hope these negotiations will result in a revised Tier II permit, agreed to by both parties, that results in emissions controls that can be considered better than the BART currently in the SIP submission.

Response: EPA acknowledges the notification.

Comment from Private Citizen

Comment: The comment supports Idaho's actions to improve visibility in Class I areas.

Response: EPA acknowledges the comment.

Comments from TASCO

Comment 1a: TASCO requests the EPA defer further action of the Regional Haze SIP submittal. TASCO explains that it is actively negotiating with IDEQ to resolve its challenge to IDEQ's Tier II operating permit that was issued on September 7, 2010, imposing BART controls on the Riley Boiler at the TASCO Nampa facility. TASCO is hopeful that the negotiations will result in a revised BART determination and revised Tier II operating permit by May 2, 2011. Thus, in the commenter's view, final action on the TASCO portion of the Regional Haze SIP is premature, would ignore the ongoing negotiations between TASCO and IDEQ, and would cause unnecessary administrative burden for EPA, IDEQ, and TASCO because the company expects that a new/revised Tier II permit will be

[1] Areas designated as mandatory Class I Federal areas consist of national parks exceeding 6000 acres, wilderness areas and national memorial parks exceeding 5000 acres, and all international parks that were in existence on August 7, 1977. 42 U.S.C. 7472(a). In accordance with section 169A of the Clean Air Act, EPA, in consultation with the Department of Interior, promulgated a list of 156 areas where visibility is identified as an important value. 44 FR 69122 (November 30, 1979). The extent of a mandatory Class I area includes subsequent changes in boundaries, such as park expansions. 42 U.S.C. 7472(a). Although states and Tribes may designate as Class I additional areas which they consider to have visibility as an important value, the requirements of the visibility program set forth in section 169A of the Clean Air Act apply only to ''mandatory Class I Federal areas.'' Each mandatory Class I Federal area is the responsibility of a ''Federal Land Manager.'' 42 U.S.C. 7602(i). When we use the term ''Class I area'' in this action, we mean a ''mandatory Class I Federal area.''.

negotiated, issued and submitted to EPA. The commenter urges EPA to postpone final action on the Regional Haze SIP submittal pending the outcome of ongoing negotiations between TASCO and IDEQ and until EPA undertakes a complete reevaluation of the affordability of BART controls.[2]

Response: TASCO suggests that instead of acting on the Regional Haze SIP submittal, EPA defer action until the ongoing negotiations between IDEQ and TASCO are completed and a revised BART determination for TASCO is submitted to EPA. Unfortunately, EPA cannot defer action on the Regional Haze SIP submittal. States were required to submit Regional Haze SIPs by December 17, 2007. As Idaho and a number of other states failed to meet this deadline, EPA issued a final rule finding that these states had failed to submit Regional Haze SIPs to EPA. 74 FR 2392 (January 15, 2009). Under the CAA, EPA must issue a Federal implementation plan (FIP) within two years of finding that a state has failed to make a required submission, unless the state submits a SIP and EPA fully approves the plan before promulgating a FIP. CAA section 110(c)(1). In addition, as described above, States are required to submit a SIP revision to address a new or revised NAAQS within three years after promulgation of such standards that contains adequate provisions to prevent emissions from within the state from interfering with other states' measures to protect visibility. Idaho failed to submit a complete SIP revision within 3 years of promulgation of the revised 1997 Ozone and $PM_{2.5}$ NAAQS as required by section 110(a)(1) and meeting the requirements of section 110(a)(2)(D)(i). EPA is under a court order to take final action approving the Idaho Regional Haze SIP submittal, or to otherwise take action to meet the requirements of section 110(a)(2)(D)(i)(II) regarding visibility, by June 21, 2011. See 76 FR 1581, fn 5. In addition, IDEQ submitted the Regional Haze SIP revision to EPA on October 25, 2010, and included the Tier II operating permit for TASCO. EPA is obligated to take action on that submittal unless or until such time as the State of Idaho withdraws that submittal and submits a SIP revision.

TASCO's suggestion that the Tier II operating permit will change as a result of its challenge or the ongoing negotiations is speculative. If and when a revised permit is issued sometime in the future, Idaho may submit it for EPA review and action, as appropriate. Such SIP revision must meet Federal requirements and policy on SIP revisions, including the Regional Haze rule requirement that an alternative BART determination must achieve greater reasonable progress than would be achieved through installation and operation of BART. See 40 CFR 51.308(e)(2). TASCO's comments concerning the affordability analysis are addressed below.

Comment 1.b.: TACSO also requests that EPA postpone action on the SIP for a few additional reasons. First, it states that due to confusion and threatened litigation over EPA's national inaction on the Regional Haze Rule, Idaho may be the first, or one of the first, states to obtain approval. Thus, in their view, postponement of Idaho's plan would not deviate from a national level of inactivity. TASCO questions the urgency to partially approve Idaho's Regional Haze SIP and suggests that based on the emission inventories from other states, Idaho should be a low priority.

TASCO also requests an explanation for the decision to only partially approve the Regional Haze SIP and urges EPA to postpone final action on Idaho's plan until other components are ready for EPA action.

Finally, in TASCO's view, postponement of final action is consistent with an Executive Order dated January 18, 2011 which reaffirms regulatory review principles. TASCO contends the Regional Haze SIP is out of step with current economic and political realities. Specifically the comment states that the appropriate focus for visibility improvements under the CAA should be emission reductions from significant contributors, such as natural fire and mobile sources. EPA's proposed partial approval, specifically the TASCO BART determination, ''ignores significant contributors and over regulates the minor contribution of the Riley Boiler. The proposal is not consistent with either the substance not the spirit of President Obama's EO.''

Response: There is no confusion regarding litigation over CAA section 110(a)(2)(D)(i)(II), the visibility prong of interstate transport, which is a separate legal action from litigation over EPA inaction on Regional Haze SIPs under Section 169(A)&(B). Idaho submitted the Regional Haze SIP to meet two provisions in the CAA—sections 110 and 169. As explained above, EPA must take action to meet the requirements of CAA section 110(a)(2)(D)(i)(II) regarding visibility by June 21, 2011. EPA's approval of the BART measures in the Idaho Regional Haze SIP submittal fulfills this obligation. EPA notes that the existence of any confusion regarding the timeline for EPA action on the Regional Haze SIPs is irrelevant to the question of whether the Regional Haze SIP submittal meets the requirements of the CAA or the regional haze program and has no impact on the statutory deadlines by which EPA must act. EPA intends to propose action on the remaining elements of the Idaho Regional Haze SIP submittal as expeditiously as possible, but finds no reason to delay action on the BART provisions.

Regarding TASCO's comment that this SIP action should be a low priority based on emission inventories from other states, EPA notes that BART obligations and the deadlines for taking action under the CAA apply regardless of the state-to-state relative emission inventories. Under the Regional Haze Rule, each state is required to address its contribution to visibility impairment in Class I areas. See *e.g.* 40 CFR 51.308(d)(3). In addition, while the Regional Haze Rule requires states to identify all anthropogenic sources of visibility impairment in developing its long-term strategy, Congress placed special emphasis on the use of retrofit controls for certain sources, such as the TASCO facility's Riley Boiler. IDEQ accordingly carefully considered the use of such controls at TASCO and determined that controls were cost-effective, would improve visibility, and were an appropriate measure for assuring reasonable progress toward the national goal.

The Executive Order identified by the commenter, EO 13563, provides that ''[o]ur regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation * * *. It must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends * * *'' While EPA's compliance with EO 13563 is not subject to judicial review, EPA has complied with the EO in this action approving IDEQ's Regional Haze SIP submittal. First, we note that EPA's Regional Haze Rules provide substantial flexibility to the states in meeting the BART requirements in the CAA while still ensuring that reasonable progress towards the national goal is made. Second, TASCO's argument that EPA has ignored the contribution of other sources to visibility impairment in approving IDEQ's BART determination misrepresents EPA's role in evaluating a state's BART determination. The CAA provides no basis for EPA to disapprove

[2] At TASCO's request EPA and IDEQ had a phone conversation with a TASCO representative on May 16, 2011, followed by a letter to the EPA dated May 25, 2011, in which TASCO reiterated its request that EPA postpone final action.

a BART determination as overly stringent because a state has ignored other sources of impairment in its SIP.

Comment 2: On September 7, 2010, IDEQ issued a Tier II operating permit to TASCO that imposed both SO2 and NOx BART controls on the Riley Boiler at the TASCO Nampa facility and on October 12, 2010, TASCO filed a contested petition with the IDEQ challenging the reasonableness of the SO2 and NOx BART controls selected. In its comments to EPA, TASCO summarized the basis for its challenge at the state level to the Tier II operating permits.

Comment 2a: IDEQ failed to consider the 5-factors required by the CAA in choosing BART for SO2 and NOx emissions including the degree of improvement in visibility from the use such technology and the cost of compliance.

Response: The Riley Boiler at TASCO, Nampa, is a BART-eligible source subject-to-BART. Contrary to the commenter's claim, and as fully described in the **Federal Register** notice, IDEQ did consider the 5-factors in its BART determination for particulate matter, SO2 and NOx. See 76 FR 1586–1589. After determining the available control technologies, the five factors are: 1) Cost of compliance; 2) Energy and non-air environmental impacts; 3) any pollution control equipment in use at the source; 4) the remaining useful life of the facility; 5) the degree of improvement in visibility which may reasonably be anticipated to result from the use of such technology.

Comment 2b: IDEQ solely relied on conservative modeling results and excluded other relevant evidence resulting in an unreasonable BART selection for TASCO's Riley Boiler.

Response: While its not clear if TASCO is suggesting that EPA should disapprove IDEQ's BART detemination on these grounds, we disagree that IDEQ relied solely on conservative modeling results. Air quality dispersion modeling was used by Idaho for two purposes: to identify sources subject to BART and to estimate visibility improvement resulting from implementation of technically feasible BART control options. In the context of this comment, TASCO does not appear to contest IDEQ's identification of sources subject to BART, but rather the projection of improvement in visibility from implementation of BART.

To provide a consistent determination of baseline to future conditions of source specific visibility impacts, Idaho correctly used dispersion modeling. See 76 FR 1585 and EPA's evaluation of WRAP modeling in EPA's WRAP TSD, Section 6.A. The model Idaho used is consistent with BART Guidelines Appendix Y, (III)(3) which recommends use of modeling for individual source attribution with the CALPUFF model. See Appendix F, BART Modeling Protocol of the SIP submittal, (p. 30) for the application of the CALPUFF model.

EPA approved the BART-subject Modeling Protocol that was used by Idaho, Oregon and Washington in their determinations of which BART eligible sources are subject to BART. EPA's evaluation of BART modeling can be found in the WRAP TSD, Section 7 (p. 51) and Appendix F of the Idaho Regional Haze SIP submittal, (p. F–30).

Comment 2c: Evidence overlooked by IDEQ to support a more reasonable outcome for TASCO BART: The Riley Boiler is located over 100 miles and in the opposite prevailing west to east wind direction from Hells Canyon, Eagle Cap, and Strawberry Mountain Wilderness Areas.

Response: Prevailing winds and distance do not necessarily determine the maximum visibility impact of a specific source. Many meteorological factors need to be considered in determining visibility impact, thus the use of dispersion modeling for determining impact. See 40 CFR 51, Appendix Y (BART Guidelines, Section III and Section IV.D, 5.

Dispersion modeling demonstrates maximum impact of TASCO Nampa emissions are in the Eagle Cap Wilderness Area. Commenter has not provided any additional information or evidence to refute that determination.

Comment 2d: The Riley Boiler is a small industrial boiler not subject to the mandatory approach of Appendix Y BART Guidelines.

Response: The commenter is correct that IDEQ was not required to follow the EPA BART Guidelines at 40 CFR part 51, Appendix Y in making its BART determination. However, as explained in the BART Guidelines, the Guidelines establish an approach to implementing the BART requirements in the Regional Haze Rule, and that EPA believes the procedures in the guidelines should be useful to the States in all BART determinations.

Comment 2e: The Riley Boiler is the only sugar beet processing factory subject to BART.

Response: Whether or not the Riley Boiler is the only U.S. sugar beet processing factory subject-to-BART is not relevant to the question of whether IDEQ reasonably concluded that the boiler met the definition of a BART-eligible source and that the boiler could reasonably be anticipated to cause or contribute to any visibility impairment at a Class I area. Fossil-fuel boilers of more than 250 MBtu/hr heat input are potentially subject to BART, regardless of the type of industrial facility at which they are located. As explained in the notice of proposed rulemaking, IDEQ followed the BART evaluation process to identify the BART-eligible sources within the state boundaries, and determined, based on its modeled impacts, that TASCO could be reasonably anticipated to contribute to visibility impairment at the Eagle Cap Wilderness Area. 76 FR 1586.

Comment 2f: TASCO states that the overall contribution of Idaho stationary sources to visibility impairment from SO2 and NOx is small. Most impairment in Idaho Class I areas originates from outside the State. The commenter also notes that the Riley Boiler accounts for only a very small fraction of SO2 and NOx emissions in Idaho.

Response: By definition, regional haze means visibility impairment that is caused by the emissions of air pollutants from numerous sources located over a wide geographic area. 40 CFR 51.301. As a result, to make reasonable progress towards the national goal, states may be required to control emissions from sources that account individually for only a small fraction of the total emissions contributing to visibility impairment. As required by the CAA and EPA's regulations, the state must undertake a BART determination for certain sources such as TASCO that are reasonably anticipated to cause or contribute to any visibility impairment. The percent contribution of a specific BART eligible source to total Statewide or region-wide emissions is not a factor in determining whether that source can be considered to contribute to visibility impairment. See 40 CFR 51.308(e). To assess whether the impact of a single source is sufficient to cause or contribute to visibility impairment at any Class I area, Idaho selected a contribution threshold of 0.5dv, the upper bound for such a threshold. See 70 FR 39104, 39161 (July 6, 2005). Given this, IDEQ determined that TASCO Nampa exceeded the 0.5dv threshold and therefore correctly determined that the facility is subject-to-BART. The Riley Boiler's relative percent contribution of SO2 and NOx emissions in Idaho is not a factor in determining whether it is exempt from meeting the BART obligations of 40 CFR 51.308(e).

Comment 2g: By relying on conservative modeling results, IDEQ failed to adjust its conclusions in light of TASCO's source apportionment modeling that suggests the IDEQ

modeling greatly overestimates visibility impacts of the Riley boiler.

Response: TASCO did not provide the TASCO source apportionment modeling results referred to in its comments. Thus, EPA cannot evaluate the credibility of the TASCO modeling, nor the significance of results.

However, in EPA's view, Idaho appropriately used CALPUFF modeling, as recommended by the BART Guidelines (Appendix Y of the Regional Haze Rule) to determine visibility impacts from TASCO. The modeling was conducted in accord with the BART Modeling Protocol, ''Modeling Protocol for Washington, Oregon, and Idaho: Protocol for the Application of the CALPUFF Modeling System Pursuant to the Best Available Retrofit Technology (BART) Regulation.'' This protocol was developed by Region 10 states and EPA Region 10 to provide consistency in decision making across Idaho, Oregon, and Washington in assessing the absolute and relative contribution of sources of visibility impairment. By providing for consistent estimates, the use of CALPUFF and specific modeling protocols ensures that sources are assessed equitably across a region. See 76 FR 1586. See also response to comment 2.b. above.

Comment 2.h: IDEQ failed to consider the shutdown of three coal-fired pulp dryers at the Nampa facility in 2007.

Response: Contrary to the comment, IDEQ did consider TASCO's shutdown and replacement of three coal-fired pulp dryers in the Regional Haze SIP submittal. However, the shut-down of other units at a facility is not a consideration to be taken into account in a BART determination. The BART determination for the Riley Boiler must be made independent of other control activities at the TASCO Nampa facility or other TASCO facilities located in Idaho.

Idaho did account for the shutdown of the pulp dryers in their assessment of baseline conditions at the Eagle Cap Wilderness Area. Idaho used the CALPUFF model results and applied scenarios with both the pulp dryers operating and not operating. See Table 10–11 of the SIP Submittal which provides the visibility impact of three scenarios: baseline with pulp dryers operating, baseline with pulp dryers shutdown, and BART implementation for NO_X and SO_2 on the Riley Boiler.

Shutdown of the pulp dryers resulted in a reduction in days over 0.5 dv over a three year period from 127 days to 97 days. Implementation of NO_X and SO_2 BART reduced the number of days over 0.5 dv to 3 days. Implementation of BART results in a significantly greater improvement in visibility than just the shutdown of the pulp dryers.

Comment 2.i: IDEQ failed to consider the additional emission reductions from TASCO's Nyssa, Oregon, shutdown in 2005.

Response: TASCO Nyssa, Oregon facility is not located in Idaho and not subject to Idaho's jurisdiction. Oregon has recognized the emission reductions associated with the shutdown of the TASCO Nyssa facility in their Regional Haze SIP. See Oregon Regional Haze SIP, Chapter 10.

Comment 2.j. The comment states that the costs of compliance are significant and could adversely affect operations at the Nampa facility. Installation of BART will require $15 million capital and annual operating expenses of over $644,000.

Response: In the TASCO BART analysis in the SIP submittal, Appendix F, the capital cost and annual costs for SO_2 and NO_X level BART control were presented as follows from Table 31 and Table 35 of Appendix F and TASCO BART Determination, Appendix D:

	Capital cost	Annual costs	Cost effectiveness
Dry FGD for SO_2	$12,970,000	$2,521,000	$2,163/ton
LNB/OFA for NO_X	4,875,000	860,000	1270/ton
Total BART Costs	17,845,000	3,381,000	.....

Idaho determined the cost effectiveness of all technically feasible BART control options for SO_2 and NO_X based on these capital investment and annual operating expenses. See Table 31 and Table 35 of Appendix F, TASCO BART determination, of the SIP submittal. The final BART determination of Low NO_X Burners with Over Fire Air (LNB/OFA) for NO_X at a cost of $1270/ton is reasonable when compared to other BART determinations across the country. The final BART determination of Dry Flue Gas De-sulfurization (Dry FGD) for SO_2 with a cost of $2163/ton is also reasonable.

The cost estimates in the SIP submittal differ (are higher) from the cost estimates provided in TASCO's comment letter. As explained in more detail below, while not required to do so, at IDEQ's request, EPA conducted an evaluation of whether TASCO could afford the BART controls and determined that it could afford the controls and remain a viable entity. EPA's evaluation of whether TASCO could afford the BART level control technology was based on the higher cost numbers in the SIP submittal. The lower costs in the TASCO comment letter would suggest TASCO could more readily afford the BART controls.

Comment 2.k. The degree of visibility improvement anticipated from BART is not measurable and does not justify the significant cost.

Response: We disagree that the visibility improvement anticipated from the use of BART at TASCO is not measurable. As explained in response to Comment 2.g. above, Idaho used the recommended dispersion model, CALPUFF, with a modeling protocol that was developed by EPA, Region 10 and the States of Idaho, Oregon and Washington to determine the improvements in visibility from the installation and operation of BART control technology. That model demonstrates significant improvement in visibility in the Eagle Cap Wilderness Area and other Class I areas as a result of BART controls on the TASCO Nampa facility. Implementation of Dry FGD for SO_2 control will reduce the number of days with impairment greater than 0.5 dv in the Eagle Cap Wilderness Area from 97 to 51 days over a 3 year period (with the pulp dryers shutdown). Implementation of LNB/OFA for NO_X control will reduce the number of days with impairment in the Eagle Cap Wilderness Area from 97 to 56 days over a 3 year period (with the pulp dryers shutdown). See Table 32 and Table 37, Appendix F of the Idaho Regional Haze SIP submittal and 76 FR 1585. Combined SO_2 and NO_X BART control will reduce the number of days over a 0.5 dv from 97 to 3 days over a 3 year period (with the pulp dryers shutdown). See Table 38 of Appendix F for the Idaho Regional Haze SIP submittal. As explained in response to Comment 2.j. above regarding costs of compliance, the cost associated with installation and operation of BART at TASCO Nampa, are not excessive and are comparable to the costs for other BART determinations across the country.

Comment 3: TASCO comments that IDEQ's approach to the BART determination for the Monsanto/P4 facility confirms the flexibility, discretion and streamlining that states are afforded in the BART process. The comment points out that the BART-subject kiln at the Monsanto/P4 facility is a significantly larger emission source than TASCO's Riley Boiler and has greater visibility impacts, but that IDEQ determined and EPA proposed to approve a BART determination for Monsanto/P4 that is less rigorous and costly than TASCO's. The comment further states that the BART determination that EPA proposed to approve for Monsanto/P4 allows a significant increase in potentially visibility impairing NO_X emissions while EPA also proposed to approve a BART determination for TASCO that reduces emissions overall. The comment also contrasted the visibility improvement days predicted to result from the BART controls at TASCO Nampa facility versus the less number of visibility improvement days predicted to result from the required emission controls at Monsanto/P4 facility.

Response: EPA does not view TASCO's comment as supporting more stringent regulation of Monsanto/P4, but rather as presenting an argument that it should not be required to install BART controls that achieve tighter limits or greater improvements in visibility than other BART facilities in Idaho. EPA disagrees that IDEQ should impose BART controls at TASCO based on the results of its BART determination at another facility. A BART determination is made on a case-by-case basis, which by definition is based on facility-specific considerations.

EPA disagrees that IDEQ provided flexibility to Monsanto/P4 in the BART determination for the Rotary Kiln that was not provided TASCO. Due to the nature of the process at Monsanto/P4 (*i.e.* limited temperature range) and existing control technology for SO_2 and PM, no technically feasible control technology is available. Thus, BART for the Rotary Kiln is 'no additional control' and no emission limitations were established in the Idaho issued operating permit. In contrast, the TASCO Riley Boiler is a traditional coal-fired industrial boiler and technically feasible control options exist and are cost-effective.

EPA does not understand TASCO's comment that there would be the potential for a 2198 t/yr increase in NO_X emissions from the Rotary Kiln based on the Monsanto/P4 BART determination. Since no additional control was determined to be BART, there is no potential to increase emissions since the existing emission limitations and design parameters at the facility will limit the production of sintered phosphate ore and limit NO_X emissions to these production levels.

4. Comment: TASCO stated that EPA's review of the costs of compliance and affordability of BART controls for the Riley Boiler was flawed:

Comment 4.a. TASCO comments that ''EPA concluded that since the company could fund the significant expense, the selected BART controls were affordable and indicates that because the EPA focused on the company's ''financial status and health,'' as well as whether the company could afford the controls and ''remain viable'', EPA applied an inappropriate and arbitrary standard of review under EPA's BART regulations and guidance. TASCO also states that ''EPA observed in its analysis, for example, that TASCO failed to be proactive and set aside funding for BART. EPA commented that TASCO should have been aware that ''a decision not to proactively address BART costs prior to the issuance of a permit could make funding the BART related costs difficult.'' TASCO also commented that EPA placed 'substantial weight' on the statements of TASCO's auditors that EPA's interpretation misconstrued the Auditor's report and ''EPA conveniently relied upon the auditor's silence regarding the BART issues to support their flawed conclusion.''

Response: The EPA BART guidelines, specifically allow, but do not require, affordability to be considered when determining BART. 70 FR 3917. The BART Guidelines indicate that there may be unusual circumstances that justify consideration of the plant and economic effects of requiring the use of a given control technology. The Guidelines suggest that economic effects include the effect on product prices, market shares and profitability of the source and that where there are special circumstances that are determined to affect plant operations, conditions of the plant and economic impacts of requiring controls may be considered. Id. The guidelines do not require that a specific method be used to conduct an affordability analysis nor do they specify a specific standard of review.

Thus, when making a BART determination the State may take into account the economic effects of requiring a particular control technology and may consider any resulting economic effects that are determined to have a severe impact on the plant's or company's operations. In this case, TASCO indicated to IDEQ that affordability was a critical element in the BART determination and IDEQ subsequently requested EPA to conduct an affordability analysis.

After considering a variety of factors, EPA determined that TASCO could afford to fund the BART controls and explained its reasoning in a separate report that was provided to IDEQ. See Executive Summary (Exec. Sum.) of the Affordability Analysis of the Amalgamated Sugar Company LLC's Affordability Claim with Respect to the Best Available Retrofit Technology (BART) for the Riley Boiler at the NAMPA, Idaho facility, February 12, 2010. (Affordability Analysis) (The Executive Summary, included in Docket for this rulemaking, is available to the public but the Affordability Analysis itself contains information claimed as Confidential Business Information and is not available for public review.) [3]

Regarding TASCO's concerns about EPA's statement that TASCO should have been aware that ''a decision not to proactively address BART costs prior to the issuance of a permit could make funding the BART related costs difficult'', TASCO appears to have taken EPA's statements out of context. The discussion in EPA's Affordability Analysis about how TASCO appears to have handled its finances as it relates to any prospective funding of BART was historical in context. EPA is aware that TASCO had no financial or legal obligation to fund the BART costs prior to issuance of a permit and/or SIP by IDEQ, or a FIP by EPA, as indicated in the Executive Summary (See Affordability Analysis, p.2). Since this issue was historical in context, it provided background for, but did not form a basis to determining whether TASCO could afford paying for BART.

TASCO is correct in stating ''EPA placed 'substantial weight' on the statements of TASCO's auditors.'' (Affordability Analysis, pp. 37–38). As explained in the Affordability Analysis, EPA recognized that the auditor should have considerable knowledge of TASCO's operations; TASCO, Snake River Sugar Company (SRSC) and grower's relationships; external conditions that could impact TASCO; BART cost estimates and TASCO's ability to continue as a going concern, and felt that the auditor would be well informed about the companies' financial condition. Affordability Analysis pp. 32–28. However, as is evident throughout the Affordability Analysis,

[3] The BART Guidelines specifically recognize that an affordability review must preserve the confidential nature of sensitive business information. 70 FR 39171.

the auditor's statements are but one piece of the information EPA considered in its affordability analysis. See Affordability Analysis Exec. Sum. P.2; and Part II.

Furthermore, a reading of Part 2, Section F in the Affordability Analysis in its entirety demonstrates that EPA did not rely on the auditor's silence regarding the specific BART costs to support the conclusion that TASCO could afford the BART controls, but rather identified specific audit related issues that in the first instance could be relevant in determining whether TASCO could, or could not afford the BART related costs. These audit related issues included: the entity continuing as a going concern; subsequent events as they relate to an audit; and the type of opinion (and its contents) expressed by the auditor. (Affordability Analysis, pp. 35–37) The Affordability Analysis demonstrates that EPA was cognizant of the possible implications regarding whether certain issues were, or were not explicitly addressed by the auditor in the company's audited financial statements. As the Affordability Analysis explains, ''In addition, even where the audited financial statements and auditor's report do not provide explicit confirmation of the entity's claims, understanding why these issues are absent from the auditor's report and financial statements can also provide important insight with respect to analyzing the entity's claims.'' (Affordability Analysis p.32)

Comment 4.b. TASCO comments that EPA ignored information from TASCO. More specifically, TASCO states ''The effects that this expenditure would have on 'profitability', 'market share', 'plant operations' and position relative to 'competing plants' are clearly fundamental to the evaluation. EPA ignored information from TASCO on the unusual circumstances within the sugar beet industry and the effects on the Nampa plant operations and costs, including its ability to compete in the U.S. sugar market.'' TASCO further states that to the extent TASCO's circumstances were considered, EPA's analysis considered the overall economics of TASCO, the company and its related entities, not the conditions at the Nampa facility or the economic effects of requiring controls there. The direct effects on TASCO's Nampa plant operations were underestimated or ignored by EPA. TASCO also comments that EPA dismissed the localized effects on the specific plant operations at Nampa and instead focused on an assessment of the TASCO business structure.

In commenter's view, EPA's notion of spreading cost throughout the Idaho sugar beet farmers is flawed and defies the realities of the sugar beet industry and TASCO's operations and underestimates the extent of the adverse impacts [of the BART determination]. TASCO states that reduced payments to growers in order to fund BART controls at Nampa will result in decreased acreage planted in sugar beets throughout Idaho. EPA unrealistically assumed that growers will continue to plant sugar beets, and ignored the declining trend in acreage planted in sugar beets.''

Referring to EPA's affordability analysis, TASCO commented that EPA failed to consider whether competing plants in the same industry are required to install BART controls and asserts that they know of no other plant in the sugar industry in the US that is required to install BART control and ignores information from TASCO about the uniqueness of imposing BART on a small industrial boiler relative to competing plants in the sugar beet industry.

Finally, TASCO described the closure of TASCO's Nyssa factory ''as evidence of the vulnerability and actual impact of plant operations from diminished sugar beet acreage. TASCO also highlighted the 31% decline in sugar beet harvest between 2007 and 2008 and EPA downplayed these plant specific impacts, and emphasized other information to conclude that TASCO, the company, is economically stable.''

Response: In determining whether TASCO could afford the BART level controls, EPA considered a variety of information, including but not limited to information provided by TASCO. As explained in the Executive Summary, the analysis considered a number of factors including the estimated capital and operation and maintenance costs, the estimated BART compliance date, TASCO's ability to continue as a viable company, the business/financial relationship between TASCO and the Snake River Sugar Company (SRSC) and other factors. The analysis specifically included information provided by TASCO. (Exec. Sum. p. 2)

EPA encouraged TASCO to provide any additional substantive information to substantiate its claims regarding affordability. However, TASCO never provided specific documentation or information that substantively demonstrated how the BART costs would adversely impact the Nampa facility specifically or that substantively supported their affordability claim. For example, the company failed to provide information regarding the minimum annual input of sugar beets needed for each facility or how BART related costs would specifically impact the number of growers. The Analysis explained that ''based on the available information, it appeared that TASCO's conclusion that less growers necessarily equals less revenue is not supported.'' Affordability Analysis p. 25–26. The comments also failed to provide substantiated information regarding these items. Additionally, as mentioned in the Affordability Analysis, when making its initial affordability claim TASCO stated that ''[a] very large consideration of this [BART determination] analysis is the ongoing viability of the Nampa facility and TASCO as a whole.'' (Affordability Analysis p. 15) Thus, TASCO itself recognized the economic status of the company as a whole was relevant.

TASCO's comment also expressed concern with EPA's observation that TASCO could spread the cost of controls among sugar beet growers throughout Idaho. The comment stated that EPA unrealistically assumed that growers will continue to plant sugar beets, and ignored the declining trend in acreage planted in sugar beets. However the comment fails to substantiate its claims that reduced payments to growers would necessarily result in decreased acreage planted in sugar beets in Idaho or to refute EPA's assumptions. The Affordability Analysis indicated EPA's perspective on this issue and explained that a sugar beet grower faces a number of choices in deciding whether or not to grow sugar beets. EPA considered how charging the capital cost for BART controls to the growers could affect their decision to continue growing sugar beets. But, as explained, EPA cannot make any determination as to whether any capital cost charged to a grower will determine whether that grower decides not to grow sugar beets (*e.g.,* move from sugar beets to an alternative crop). EPA also refers to the Patterson study (2009) which compared sugar beets, at different price and yield levels, to alternative crops. Affordability Analysis, p. 27. Furthermore, the analysis also recognized that an additional factor a grower must take into consideration in deciding not to grow sugar beets is that ''member grower who decides not to grow, *i.e.,* to withdraw from the Cooperative (SRSC), would face a significant monetary charge from SRSC.'' Id. Another implication is that the grower has crop alternatives though these other crops may not provide a long-term solution. Id. As part of its review EPA explained that ''An analysis of the economics of growing sugar beets in southern Idaho, released in January

2009, provides important insight into recent sugar beet prices paid to growers:

> Sugar beet prices in recent years have been relatively stagnant, while input costs have increased. Sugar beet prices over the past ten years averaged approximately $39.60 per ton, ranging from a high of just over $44 to a low of just over $36 according to data from the USDA. A similar situation also existed for most other commodities grown in southern Idaho, with no crop having a consistent economic advantage. But when grain and forage prices spiked to unprecedented levels in 2007, the equilibrium was eliminated and growers saw an opportunity to capitalize on the high returns that these crops offered. Crops that were often viewed as money losing rotation crops by potato and sugar beet growers had become the most profitable crop alternatives available to growers. But high grain prices were short-lived with grain prices declining rapidly after the 2008 harvest. Affordability Analysis p. 22–23.

Regarding TASCO's comment about the closure of the TASCO Nyssa, Oregon plant, in conducting the Affordability Analysis EPA considered and weighed all information it had available in coming to its conclusion. If it appears that EPA downplayed certain impacts, it is because there was additional substantive information as summarized above and described throughout its analysis that provided the basis for EPA's affordability conclusion, and TASCO did not provide substantive information to support its assertions. For example, with respect to TASCO's comment regarding the closing of the Nyssa factory: TASCO stated that ''the economic benefit to the grower-owned Cooperative of running three factories compared to four is significant and cannot be ignored.'' (Affordability Analysis p. 27.) TASCO did not provide plant specific substantive information that would enable EPA to validate TASCO's stated concerns about BART impacts to the Nampa factory and the other two factories, and to the growers, *e.g.,* plant capacities, plant operating margins, *etc.*

Comment 4.c.: TASCO commented that the estimated cost of compliance will exceed $75,000 per grower that supplies sugar beets to the Nampa factory, based upon an estimated capital cost of $15,690,000. TASCO stated that this amount exceeds the estimated annual profit per grower which is conservatively $65,400.

Response: There are several parts to TASCO's comment. First, TASCO indicates that the $75,000 BART related cost per grower is charged to the Nampa growers as a one-time charge. However, when as part of its analysis EPA calculated BART capital costs to the growers (Nampa only growers, and to all growers), EPA amortized these costs over two different time periods based on information provided by TASCO. See Affordability Analysis p. 26; Table 6, p. 29; p. 36. Second, TASCO's most recent capital cost estimate ($15,690,000) is $2.11 million less than the capital cost EPA used for the Affordability Analysis ($17.8 million) which was based on TASCO's BART Analysis. See Regional Haze SIP submission, Appendix F, Table 31 and Table 35. Furthermore, the number of growers for the Nampa factory and in total—(see TASCO comments, footnote 8) are greater than those used in the Affordability Analysis. See TASCO comment footnote 8 compared to Affordability Analysis Table 6, p. 29. Mathematically this would indicate that any new calculations made using this latest information would mean lower BART related charges passed on to each grower. Third, as explained in EPA's analysis, allocating the BART capital costs only to the Nampa factory growers and not to all the growers is a business decision made by TASCO. Affordability Analysis p. 26. Using the TASCO figures provided in the comment, calculated for the two amortization periods of six years or nine years, the amortized BART capital cost to all growers would amount to less than $0.45 per ton of sugar beets or less than $0.30 per ton of sugar beets, respectively, and if the cost was the allocated only to the Nampa growers it would be approximately $1.75 and $1.17 respectively—amounts less than the figures indicated in EPA's original analysis. See Affordability Analysis Table 6.

Comment 4.d: EPA failed to consider whether competing plants in the same industry are required to install BART controls and asserts that they know of no other plant in the sugar industry that is required to install BART controls and ignores information from TASCO about the uniqueness of imposing BART on a small industrial boiler relative to competing plants in the sugar beet industry.

Response: The BART Guidelines provide that an affordability analysis may consider whether other competing plants in the same industry have been required to install BART controls. 70 FR 39171. However, in this instance EPA's analysis determined that regardless of the number of other facilities in this industry subject to BART, the cost for TASCO to implement the controls determined to be BART are affordable and would not significantly impact its continued economic viability. Additionally, as explained above, TASCO did not provide or substantiate its claims to demonstrate that it would operate at a competitive disadvantage and thus, EPA was not able to determine the relative competiveness between TASCO and other sugar beet processors.

Comment 5: TASCO's comment letter to EPA included statements regarding the additional information it has outlined for IDEQ in the negotiations with the State to resolve the Tier II operating permit challenge.

Response: This comment relates to the pending negotiations between TASCO and the State. At this point in time EPA does not know how IDEQ will evaluate or use the additional information provided to it. If the State revises the TASCO operating permit and submits it to EPA, at that time EPA will evaluate IDEQ's decision and the information upon which it is based.

Wyoming Outdoor Council Comments

Comment 1: The commenter requests that a BART determination be conducted and BART emission limitations be imposed for two additional sources in Idaho: Nu West/Agrium facility (Nu West) in Soda Springs and the J.R. Simplot Don Plant (J.R. Simplot) in Pocatello. The commenter asserts that given that the Nu West and J.R. Simplot plants are directly upwind and in close proximity to Wyoming Class I areas, it seems clear they should merit special attention through a requirement for the installation of BART. The data developed by the State of Wyoming for its draft Regional Haze SIP also make it clear that Idaho sources of air pollution are one of the most significant contributors to visibility impairing haze in Wyoming Class I areas. The commenter also suggests the 0.5 dv impact threshold used to determine whether a BART eligible source is subject to BART, was determined for only Class I areas located in Idaho. The comment then suggests concern that all seven Wyoming Class I areas, and especially the Bridger and Fitzpatrick Wilderness Areas, are directly downwind of these plants (Nu West and J.R. Simplot), and in quite close proximity to them. Thus, absent empirical data to the contrary, there should be no finding that the J.R. Simplot and Nu West plants are not significantly impacting Wyoming Class I areas.

Response: In determining which BART eligible sources would be subject to BART, Idaho considered all Class I areas within a 300 km radius of the source, including Class I areas outside the State boundary. Air quality dispersion modeling is the preferred technique to determine a single source's impact on any Class I area. See BART Guidelines, Section I.A. As discussed

above, the modeling completed by Idaho demonstrates that BART-eligible sources located in Idaho, other than those identified in the SIP submittal as exceeding the BART contribution threshold, do not significantly impact Class I areas within a 300 km radius of the source, including Class I areas in Wyoming and Montana. Furthermore, IDEQ consulted with Wyoming (Wyoming Department of Environmental Quality) and other neighboring states regarding its emission reduction contribution. This consultation included the review of major contributing sources of air pollution, interstate transport of emissions, major emission sources believed to be contributing to visibility impairment, and whether any mitigation measures were needed. See Chapter 13.2.1 of the Idaho Regional Haze SIP submittal.

As explained in the Idaho Regional Haze SIP submission, Idaho considered whether these two BART eligible sources were subject-to-BART. See Regional Haze SIP submittal Appendix F, Table 3 for a discussion of the Nu West modeling to determine whether it met the threshold for being subject to BART. The modeling shows the impact of Nu West in Class I areas within a 300 km radius, including the Bridger and Fitzpatrick Wilderness Areas. The SIP submittal explains that over a three year period (2003–2005) there were no days where Nu West had an impact of greater than 0.5 dv, the Idaho threshold for sources being subject to BART. The greatest impact occurred in the Bridger Wilderness Area with a value of 0.051 dv, or approximately 1/10 the level of the 'BART subject' threshold.

A discussion of the J.R. Simplot modeling to determine whether it met the threshold for being subject to BART can be found in the SIP submittal, Appendix F, Table 11 (page 198 of Appendix F of the SIP submittal). The modeling shows the impact of J.R. Simplot in Class I areas within a 300 km radius of the plant, including the Fitzpatrick Wilderness Area. Over a three year period (2003–2005) there were no days where J.R. Simplot had an impact of greater than 0.5 dv in the Fitzpatrick Wilderness Area.

The modeling showed that neither facility met the 0.5 dv contribution threshold. Therefore, IDEQ reasonably determined that neither Nu West nor J.R. Simplot were subject to BART. As explained in the proposed rulemaking EPA agreed with the State's determination in this regard.

Comment 2: The commenter believes that Region 10 should make good on its finding that the 0.5 dv threshold is not adequate to avoid the requirement for BART to be installed because there is likely no objective basis to claim that the J.R. Simplot and Nu West plants have ''relatively limited impact on visibility'' when it comes to Wyoming Class areas. If the greatest improvements due to BART being required on the Monsanto/P4 Plant are seen at the Teton Wilderness Area, it seems very likely that even greater benefits would be seen at the Bridger and Fitzpatrick Wilderness Areas if BART were required for the J.R. Simplot and Nu West plants. Consequently BART should be required for these sources of emissions.

Response: As explained above, the methods and process IDEQ used to determine that 0.5dv is an appropriate threshold to use to determine if an individual source is subject to BART are consistent with the Regional Haze Rule. For the reasons explained in the **Federal Register** notice describing the rationale for the proposed action, while Idaho failed to provide an adequate rationale for selecting the 0.5 dv threshold for determining BART eligible sources subject to BART, EPA determined that even with a more robust rationale the 0.5 dv threshold was acceptable. 76 FR 1585. Additionally, in reviewing the modeling results for Nu West and J.R. Simplot for determining whether they are subject to BART, it is apparent that Idaho would had to have established a threshold below 0.1 dv in order to include these additional sources subject to BART. A 1.0 dv change in visibility is usually a small but perceptible scenic change. (See Interagency Monitoring of Protected Visual Environments (IMPROVE) newsletter, Vol. 2 No. 1, Winter 1993). In EPA's view, generally a 0.1 dv threshold is unreasonable because the human eye could not perceive this change in visibility impairment and yet would require significant expenditure of resources to implement BART.

The Wyoming Regional Haze SIP submittal that was submitted to EPA Region 8 does not identify any sources in Idaho that significantly impact Class I areas in Wyoming. In developing the Reasonable Progress Goals for Class I areas in Wyoming, the Wyoming SIP relies on the consultation process in the WRAP for establishing emission reductions from sources located in Idaho. See Chapter 11.1 page 184 of the Wyoming SIP submittal.

III. Final Action

EPA is approving the BART measures in the Idaho Regional Haze plan as meeting the requirements of section 110(a)(2)(D)(i)(II) of the CAA with respect to the 1997 8-hour ozone and 1997 $PM_{2.5}$ NAAQS. In addition, EPA is approving portions of the Idaho Regional Haze SIP, submitted on October 25, 2010, as meeting the requirements set forth in section 169A of the Act and in 40 CFR 51.308(e) regarding BART. EPA is also approving the Idaho submittal as meeting the requirements of 51.308(d)(2) and (4)(v) regarding the calculation of baseline and natural conditions for Craters of the Moon National Monument, Sawtooth Wilderness Area, and Selway-Bitterroot Wilderness Area, and the statewide inventory of emissions of pollutants that are reasonably anticipated to cause or contribute to visibility impairment in any mandatory Class I Federal Area.

IV. Scope of Action

Idaho has not demonstrated authority to implement and enforce IDAPA chapter 58 within ''Indian Country'' as defined in 18 U.S.C. 1151.[4] Therefore, EPA proposes that this SIP approval not extend to ''Indian Country'' in Idaho. *See* CAA sections 110(a)(2)(A) (SIP shall include enforceable emission limits), 110(a)(2)(E)(i) (State must have adequate authority under State law to carry out SIP), and 172(c)(6) (nonattainment SIPs shall include enforceable emission limits). This is consistent with EPA's previous approval of Idaho's prevention of significant deterioration (PSD) program, in which EPA specifically disapproved the program for sources within Indian Reservations in Idaho because the State had not shown it had authority to regulate such sources. *See* 40 CFR 52.683(b). It is also consistent with EPA's approval of Idaho's title V air operating permits program. *See* 61 FR 64622, 64623 (December 6, 1996) (interim approval does not extend to Indian Country); 66 FR 50574, 50575 (October 4, 2001) (full approval does not extend to Indian Country).

[4] ''Indian country'' is defined under 18 U.S.C. 1151 as: (1) All land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and including rights-of-way running through the reservation, (2) all dependent Indian communities within the borders of the United States, whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a State, and (3) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same. Under this definition, EPA treats as reservations trust lands validly set aside for the use of a Tribe even if the trust lands have not been formally designated as a reservation. In Idaho, Indian country includes, but is not limited to, the Coeur d'Alene Reservation, the Duck Valley Reservation, the Reservation of the Kootenai Tribe, the Fort Hall Indian Reservation, and the Nez Perce Reservation as described in the 1863 Nez Perce Treaty.

V. Statutory and Executive Orders Review

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

In addition, this rule does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the rule neither imposes substantial direct compliance costs on Tribal governments, nor preempts Tribal law. Therefore, the requirements of section 5(b) and 5(c) of the Executive Order do not apply to this rule. Consistent with EPA policy, EPA nonetheless provided a consultation opportunity to Tribes in Idaho, Oregon and Washington in letters dated January 14, 2011. EPA received one request for consultation, and we have followed-up with that Tribe. This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it approves a state rule implementing a Federal standard.

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by *August 22, 2011.* Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: June 13, 2011.

Dennis J. McLerran,

Regional Administrator, Region 10.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart N—Idaho

■ 2. Section 52.670 is amended as follows:

■ a. In paragraph (d) by adding two entries to the end of the table.

■ b. In paragraph (e) by adding an entry to the end of the table.

§ 52.670 Identification of plan.

* * * * *

(d) * * *

EPA-APPROVED IDAHO SOURCE-SPECIFIC REQUIREMENTS[1]

Name of source	Permit No.	State effective date	EPA approval date	Explanation
*	*	*	*	*
The Amalgamated Sugar Company LLC—Nampa Factory, Nampa, Idaho.	T2–2009.0105	09/07/10 (date issued).	06/22/11 [Insert page number where the document begins].	The following conditions: 1.2 (including table), 3 (heading only), 3.1, 3.2, 3.3, 3.4 (including table), 3.6, 3.7, 3.8, 3.9, 3.10, 3.11, 3.12, 3.13, 3.15, 3.16, and 3.17. (Regional Haze SIP revision).

EPA-APPROVED IDAHO SOURCE-SPECIFIC REQUIREMENTS[1]—Continued

Name of source	Permit No.	State effective date	EPA approval date	Explanation
P4 Production, L.L.C. , Soda Springs, Idaho	T2–2009.0109	11/17/2009 (date issued).	06/22/11 [Insert page number where the document begins].	The following conditions: 1.2 (including Table 1.1), 2.3, 2.4, 2.5, 2.6, 2.7, and 2.8. (Regional Haze SIP Revision).

[1] EPA does not have the authority to remove these source-specific requirements in the absence of a demonstration that their removal would not interfere with attainment or maintenance of the NAAQS, violate any prevention of significant deterioration increment or result in visibility impairment. Idaho Department of Environmental Quality may request removal by submitting such a demonstration to EPA as a SIP revision.

* * * * * (e) * * *

EPA-APPROVED IDAHO NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Comments
*	*	*	*	* * *
Regional Haze SIP Revision.	State-wide	10/25/10	06/22/11 [Insert page number where the document begins].	The portion of the Regional Haze SIP revision relating to BART, the calculation of baseline and natural conditions, and the statewide inventory of emissions of pollutants that are reasonably anticipated to cause or contribute to visibility impairment in any mandatory Class I Federal Area.

■ 3. Section 52.672 is amended by adding paragraph (g) to read as follows:

§ 52.672 Approval of plans.

* * * * *

(g) *Visibility protection.* (1) EPA approves portions of a Regional Haze SIP revision submitted by the Idaho Department of Environmental Quality on October 25, 2010, as meeting the requirements of Clean Air Act section 169A and 40 CFR 51.308(e) regarding Best Available Retrofit Technology. The SIP revision also meets the requirements of 40 CFR 51.308(d)(2) and (4)(v) regarding the calculation of baseline and natural conditions for Craters of the Moon National Monument, Sawtooth Wilderness Area, and Selway-Bitterroot Wilderness Area and the statewide inventory of emissions of pollutants that are reasonably anticipated to cause or contribute to visibility impairment in any mandatory Class I Federal Area. The SIP revision also meets the requirements of Clean Air Act section 110(a)(2)(D)(i)(II) as it applies to visibility for the 1997 8-hour ozone NAAQS and 1997 PM2.5 NAAQS.

(2) [Reserved]

[FR Doc. 2011–15452 Filed 6–21–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 98

[EPA–HQ–OAR–2009–0927; FRL–9322–1]

RIN A2060

Mandatory Reporting of Greenhouse Gases: Additional Sources of Fluorinated GHGs: Extension of Best Available Monitoring Provisions for Electronics Manufacturing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; Grant of reconsideration.

SUMMARY: This action gives notice that EPA has initiated the reconsideration process in response to a request for reconsideration of provisions for the use of best available monitoring methods in Subpart I: Electronics Manufacturing of the Mandatory Greenhouse Gas Reporting Rule. Consequently, this action extends three of the deadlines in Subpart I related to using the best available monitoring methods provisions from June 30, 2011 to September 30, 2011.

DATES: This final rule is effective on June 30, 2011.

FOR FURTHER INFORMATION CONTACT: Ms. Carole Cook, Climate Change Division, Office of Atmospheric Programs (MC–6207J), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number (202) 343–9263; fax (202) 343–2342; e-mail address: *GHGReportingRule@epa.gov.* For technical information and implementation materials, please go to the Web site *http://www.epa.gov/climatechange/emissions/ghgrulemaking.html.* To submit a question, select Rule Help Center, then select Contact Us.

SUPPLEMENTARY INFORMATION:

Acronyms and Abbreviations. The following acronyms and abbreviations are used in this document.

BAMM Best Available Monitoring Methods
CAA Clean Air Act
CBI confidential business information
CFR Code of Federal Regulations
EPA U.S. Environmental Protection Agency
FR **Federal Register**
GHG greenhouse gas
mm millimeters
NTTAA National Technology Transfer and Advancement Act of 1995
PRA Paperwork Reduction Act
QA/QC quality assurance/quality control
RFA Regulatory Flexibility Act
SIA Semiconductor Industry Association
SBREFA Small Business Regulatory Enforcement Fairness Act
UMRA Unfunded Mandates Reform Act of 1995
U.S. United States
WWW Worldwide Web

Table of Contents

I. Background Information

II. Statutory and Executive Order Reviews
A. General Requirements
B. Submission to Congress and the Comptroller General
III. How can I get copies of this document and other related information?

I. Background Information

EPA published Subpart I: Electronics Manufacturing of the Greenhouse Gas Reporting Rule on December 1, 2010 (75 FR 74774). This subpart requires monitoring and reporting of greenhouse gas (GHG) emissions from electronics manufacturing. Included in the December 1, 2010 final rule are provisions allowing owners or operators of semiconductor manufacturing facilities the option of using and/or requesting the use of best available monitoring methods (BAMM) for specified parameters. Specifically, from January 1, 2011 to June 30, 2011, owners or operators may use BAMM for any parameter that cannot reasonably be measured according to the monitoring and QA/QC requirements of Subpart I without submitting a request to and receiving approval from the Administrator (40 CFR 98.94(a)(1)). To extend the use of BAMM to estimate emissions that occur beyond June 30, 2011, the December 1, 2010 final rule provides that owners and operators must submit a request to and receive approval from the Administrator consistent with the following:

- Requests for extension of the use of BAMM to estimate emissions that occur from July 1, 2011 through December 31, 2011 for parameters other than recipe-specific utilization and by-product formation rates for the plasma etching process type must have been submitted to EPA no later than February 28, 2011 (40 CFR 98.94(a)(2)).
- Requests for extension of the use of BAMM to estimate emissions that occur from July 1, 2011 through December 31, 2011 for recipe-specific utilization and by-product formation rates for the plasma etching process type must be submitted to EPA no later than June 30, 2011 (40 CFR 98.94(a)(3)).
- Requests for extension of the use of BAMM to estimate emissions beyond December 31, 2011 for unique and extreme circumstances must be submitted to EPA no later than June 30, 2011 (40 CFR 98.94(a)(4)).

Following the publication of subpart I in the **Federal Register**, the Semiconductor Industry Association (SIA) sought reconsideration of several provisions in the final rule, including the provisions relating to BAMM. In its Petition for Reconsideration dated January 31, 2011 (available in docket EPA–HQ–OAR–2009–0927), SIA stated that the BAMM provisions raise ''substantive compliance issues.'' In particular, SIA stated that the substantive compliance issues relate to the following aspects of the BAMM provisions: The requirement to recalculate and resubmit estimated emissions, the individual requirement-by-requirement BAMM request process, the documentation requirement, the timeframe for assembling the documentation, and the unique and extreme circumstances provision. More specifically, SIA stated that the individual requirement-by-requirement BAMM request process is cumbersome and unreasonably burdensome, and that the required documentation to support the request is excessive. Further, SIA stated that the deadlines for submitting the request to use BAMM were ''unreasonable.'' In particular, SIA stated that the June 30, 2011 deadline for the recipe-specific utilization and by-product formation rates was ''not realistic'' due to ''serious technical infeasibility issues.'' SIA also noted that the individuals who would be responsible for analyzing Subpart I, gathering information, and preparing the BAMM requests were the same individuals who would be working with EPA ''towards mutually acceptable solutions and alternatives.''

EPA has concluded that pursuant to CAA section 307(d)(7)(B) it is appropriate to extend by three months the period in 40 CFR 98.94(a)(1), during which owners and operators have the option to use BAMM in 2011 without submitting a request for approval from the Administrator. EPA has also concluded that pursuant to CAA section 307(d)(7)(B) it is appropriate to extend by three months the deadlines in 40 CFR 98.94(a)(3)(i) and 98.94(a)(4)(i), by which owners and operators may submit a request for approval by the Administrator to use BAMM in 2011 for recipe-specific utilization and by-product formation rates (recipe-specific emission factors) for the plasma etching process type, and to use BAMM to estimate emissions that occur beyond December 31, 2011 for unique and extreme circumstances, respectively. Extending the deadlines will allow EPA additional time to consider comments and take final action on a proposal that EPA is also publishing today, as discussed in more detail in the following paragraphs.

In a separate action also published in today's **Federal Register** (please refer to the proposed rule *Mandatory Reporting of Greenhouse Gases: Changes to Provisions for Electronics Manufacturing (Subpart I) to Provide Flexibility* in docket EPA–HQ–OAR–2009–0927), EPA is proposing to allow the largest semiconductor facilities the option of calculating emissions using default utilization and by-production formation rates (default emission factors) already contained in Subpart I for the plasma etching process type for a limited time period instead of calculating emissions using directly measured recipe-specific emission factors during that time period.[1] The December 1, 2010 final rule provides that the largest semiconductor manufacturing facilities are required to calculate emissions for the plasma etching process type using only directly measured recipe-specific emission factors. Other semiconductor manufacturing facilities that manufacture wafers on 300 millimeters (mm) or less in diameter are required to calculate emissions for the plasma etching process type using default emission factors provided in Tables I–3 and I–4 of Subpart I.

In the separate action also published in today's **Federal Register,** EPA is proposing to allow the largest semiconductor facilities to use the same default emission factors already used by the other semiconductor manufacturing facilities that manufacture wafers on 300 mm or less in diameter during the initial years of implementation of Subpart I in response to concerns raised by SIA in their Petition for Reconsideration regarding the individual recipe measurement approach, that is, the requirement that the largest facilities develop and use recipe-specific emission factors for etch processes. More specifically, in their Petition, SIA stated that the individual recipe measurement approach is technically impractical, burdensome, threatens intellectual property, and would hamper innovation. SIA also stated its member companies' ''strong desire to reach agreement with EPA on an alternative'' to that measurement approach. By extending the dates by which a facility may use and/or request the use of BAMM in today's final action, EPA will have additional time to consider comments and take final action on provisions in the separate action to allow the largest semiconductor manufacturing facilities to use the default emission factors already

[1] The ''largest'' semiconductor manufacturing facilities are defined as those facilities that fabricate devices on wafers measuring 300 mm or less in diameter and that have an annual manufacturing capacity of greater than 10,500 square meters (m^2) of substrate. EPA estimates that the largest semiconductor manufacturing facilities comprise 29 facilities out of 175 total semiconductor facilities. See the Electronics Manufacturing Technical Support Document available in the docket (EPA–HQ–OAR–2009–0927) for EPA's analysis.

contained in Subpart I in the initial years of implementation. In turn, this will provide a clear, consistent approach to compliance with Subpart I while EPA considers longer-term alternatives.

In today's final rule, EPA is taking no action on other issues raised by SIA in their Petition for Reconsideration. EPA is also taking no action at this time on issues raised by 3M Company in their January 28, 2011 Petition for Reconsideration of Subpart I.

Pursuant to Clean Air Act (CAA) section 307(d)(7)(B), EPA is extending the deadlines in 40 CFR 98.94(a)(1), 40 CFR 98.94(a)(3)(i), and 40 CFR 98.94(a)(4)(i) for three months; i.e., until September 30, 2011.

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today's rule final without prior proposal and opportunity for comment. We are acting pursuant to CAA section 307(d)(7)(B) to extend these deadlines in part because we are considering a change to Subpart I, which would obviate the need to conduct a BAMM process for this aspect of the rule. In addition, we are extending these provisions to allow owners and operators of affected facilities additional time to assess their facilities to determine if it will be necessary for them to apply for BAMM for any other aspect of Subpart I beyond 2011 for unique and extreme circumstances. Because we cannot predict the outcome of today's proposed rule, we have concluded that a limited extension pending final action on that proposal is appropriate so that owners and operators of affected facilities would not incur additional costs associated with applying for BAMM in advance of our final decision on this issue. It would be impracticable to go through notice and comment rulemaking to extend an imminent deadline, and it is also unnecessary because section 307(d)(7)(B) does not require notice and comment for a three-month extension pending reconsideration. Thus, notice and public procedure are impracticable and unnecessary. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B) in this instance.

II. Statutory and Executive Order Reviews

A. General Requirements

This action is not a ''significant regulatory action,'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and, therefore, not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011). For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). In addition, because the agency has made a ''good cause'' finding that this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute (*see* Section I of this preamble) it is not subject to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). In addition, this action does not impose any enforceable duty or contain any unfunded mandates as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials, as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or involve special consideration of environmental justice related issues, as required by Executive Order 12898 (59 FR 7629, February 16, 1994). Further, because the agency has made a ''good cause'' finding that this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*). This action also does not have Tribal implications because it will not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal government and Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action also is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*). EPA's compliance with these statutes and Executive Orders for the underlying rule is discussed in the December 1, 2010 **Federal Register** document.

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective June 30, 2011.

III. How can I get copies of this document and other related information?

This **Federal Register** notice is available in the docket for the final rule titled ''*Mandatory Reporting of Greenhouse Gases: Additional Sources of Fluorinated GHGs,*'' published on December 1, 2010 at 98 FR 74774, under Docket ID No. EPA–HQ–OAR–2009–0927.

All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, i.e., Confidential Business Information 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 EPA's Docket Center, Docket ID No. EPA–HQ–OAR–2009–0927, Public Reading Room, EPA West Building, Room 3334, 1301 Constitution Avenue, Northwest, Washington, DC 20460. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and

the telephone number for the Air Docket Center is (202) 566–1741.

In addition to being available in the docket, an electronic copy of this **Federal Register** notice is also available on the World Wide Web at *http://www.epa.gov/climatechange/emissions/ghgrulemaking.html.*

List of Subjects in 40 CFR Part 98

Environmental Protection, Administrative practice and procedures, Air pollution control, Monitoring, Reporting and recordkeeping.

Dated: June 15, 2011.

Lisa P. Jackson,

Administrator.

For the reasons discussed in the preamble, title 40, chapter I, of the Code of Federal Regulations is amended as follows:

PART 98—[AMENDED]

■ 1. The authority citation for part 98 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart I—[Amended]

■ 2. Section 98.94 is amended as follows:

■ a. By revising paragraph (a)(1) introductory text.

■ b. By revising paragraph (a)(3) introductory text.

■ c. By revising paragraph (a)(3)(i).

■ d. By revising paragraph (a)(4)(i).

§ 98.94 Monitoring and QA/QC requirements.

(a) * * *

(1) *Best available monitoring methods.* From January 1, 2011 through September 30, 2011, owners or operators may use best available monitoring methods for any parameter that cannot reasonably be measured according to the monitoring and QA/QC requirements of this subpart. The owner or operator must use the calculation methodologies and equations in § 98.93, but may use the best available monitoring method for any parameter for which it is not reasonably feasible to acquire, install, or operate a required piece of monitoring equipment in a facility, or to procure necessary measurement services by January 1, 2011. Starting no later than October 1, 2011, the owner or operator must discontinue using best available monitoring methods and begin following all applicable monitoring and QA/QC requirements of this part, except as provided in paragraphs (a)(2), (a)(3), or (a)(4) of this section. Best available monitoring methods means any of the following methods specified in this paragraph:

* * * * *

(3) Requests for extension of the use of best available monitoring methods in 2011 for recipe-specific utilization and by-product formation rates for the plasma etching process type under § 98.93(a)(2)(ii)(A). The owner or operator may submit a request to the Administrator under this paragraph (a)(3) to use one or more best available monitoring methods to estimate emissions that occur between October 1, 2011 and December 31, 2011 for recipe-specific utilization and by-product formation rates for the etching process type under § 98.93(a)(2)(ii)(A).

(i) *Timing of request.* The extension request must be submitted to EPA no later than September 30, 2011.

* * * * *

(4) * * *

(i) *Timing of request.* The extension request must be submitted to EPA no later than September 30, 2011.

* * * * *

[FR Doc. 2011–15650 Filed 6–21–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0330; FRL–8875–9]

2-methyl-2,4-pentanediol; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 2-methyl-2,4-pentanediol (CAS Reg. No. 107–41–5) when used as an inert ingredient as a solvent in pesticide formulations 40 CFR 180.910 and 180.930 for use on crops (pre-harvest and post-harvest) and for direct application on animals without limitations. 2-methyl-2,4-pentanediol is commonly referred to as ''hexylene glycol''. The FB Sciences, Inc., 153 N. Main Street, Suite 100, Collierville, TN 38017 submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 2-methyl-2,4-pentanediol.

DATES: This regulation is effective June 22, 2011. Objections and requests for hearings must be received on or before August 22, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0330. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Mark Dow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305– 5533; e-mail address: *dow.mark@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining

whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0330 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 22, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0330, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Exemption

In the **Federal Register** of June 8, 2010 (75 FR 32466) (FRL–8827–8), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 0E7693) by FB Sciences, Inc., 153 N. Main Street, Ste. 100, Collierville, TN 38017. The petition requested that 40 CFR 180.910 and 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of 2-methyl-2,4-pentanediol (CAS Reg. No.107–41–5) when used as an inert ingredient as a solvent in pesticide formulations applied to crops pre-harvest and post-harvest and to animals without limitations. That notice referenced a summary of the petition prepared by FB Sciences, Inc., the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue* * *.''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 2-methyl-2,4-pentanediol including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 2-methyl-2,4-pentanediol follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by 2-methyl-2,4-pentanediol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the

toxicity studies are discussed in this unit.

2- methyl-2,4-pentanediol (CAS Reg. No. 107–41–5) is an aliphatic alcohol also known as: Hexylene glycol; diolane; and 1,1,3-trimethyltrimethylene-diol. Non-pesticidal uses of 2-methyl-2,4-pentanediol include use as a chemical intermediate, a selective solvent in petroleum refining, a component of hydraulic fluids, a solvent for inks, as an additive to cement, textile dye vehicles, a lubricant and fuel additive, and as an ingredient in cosmetics and hair care products. The Food and Drug Administration (FDA) has approved of the use of 2-methyl-2,4-pentanediol as an indirect food additive such as in adhesives in contact with food under 21 CFR parts 175–178.

2-methyl-2,4-pentanediol is not acutely toxic to rats via the oral route of exposure. An Organization for Economic Cooperation and Development (OECD)–SIDS (2001) report indicates LD_{50} ranges from 2–4.47 g/kg. Acute dermal toxicity is low with dermal doses up to 2,000 milligrams/kilogram (mg/kg) that did not cause death (as cited in OECD–SIDS, 2001). It is irritating to the skin and eyes, but not a skin sensitizer in guinea pigs. It has low inhalation toxicity, with an LC_{50} of 160 parts per million (ppm) (0.772 mg/L), which is in excess of the saturated vapor concentration.

In a 90-day subchronic toxicity study, 2-methyl-2,4-pentanediol was administered by oral gavage to rats at dose levels of 50, 150, or 450 mg/kg/bw/day. In this study the functional observational battery, blood chemistry, hematological parameters and histopathological examinations were conducted. A functional observational battery test gave no indication of neurotoxicity. In both sexes, hyperplasia, hyperkeratosis, inflammatory cell infiltration and edema of the mucosa and submucosa of the stomach were observed starting at 150 mg/kg/day. These changes were indicative of a local irritative effect resulting from the oral gavage procedure. Hepatocellular hypertrophy with increased liver weight was observed at 450 mg/kg/day in both sexes, and in males at 150 mg/kg/day. In the absence of degenerative or necrotic changes these findings were considered to be adaptive responses. At 150 and 450 mg/kg/day, increased kidney weights and increased incidence of acidophilic globules in the tubular epithelium in males were suggestive of male rat specific alpha-2-microglobulin nephropathy, which is not considered as an effect relevant to humans. Observed changes were either fully or partially reversible over the 4-week recovery period. There were no adverse effects on the reproductive organs. No effects were observed at 50 mg/kg/day. A NOAEL of 450 mg/kg/day was determined for systemic toxicity because the effects described were either produced by irritation from the oral gavage procedure, or were considered adaptive responses. A range-finding 14-day study gave similar results.

No guideline reproduction studies were available for assessment, however, no adverse effects on reproductive organs (including testes, prostate, seminal vesicles, epididymis, ovaries, vagina, and uterus) were observed in the 90-day gavage study in which rats were administered 2-methyl-2,4-pentanediol at doses up to 450 mg/kg/day. Therefore, OECD SIDS concluded that no additional studies are required under the SIDS program regarding fertility. EPA agrees with this conclusion by the OECD.

In a developmental toxicity study, pregnant rats were administered 30, 300, or 1,000 mg/kg/bw/day of 2-methyl-2,4-pentanediol by gavage in 5 mL/kg of vehicle on gestation days (GD) 6–15. The NOAEL for maternal toxicity was 300 mg/kg/day based on a statistically significant reduction in group mean body weight gain and food consumption at 1,000 mg/kg/day. There was a marginal, non-statistically significant reduction in fetal body weight at 1,000 mg/kg/day. Marginally higher incidences of fetal variations, some of which were statistically significant (occipitals incompletely ossified, 21.6%; extra thoracolumbar ribs, 18.7%; and hyoid arch not ossified, 18%), occurred at 1,000 mg/kg/day. A delay in the normal ossification process was also observed in fetuses, but this was considered by the study authors to be related to reduced maternal body weight gain at this dose level. The NOAEL and LOAEL for maternal and fetal developmental toxicity were determined to be 300 and 1,000 mg/kg/day, respectively.

In another developmental toxicity study, pregnant rats received 500, 1,200, or 1,600 mg/kg/bw/day of 2-methyl-2,4-pentanediol by gavage in 10 mL/kg of vehicle on GD 6–17. At 1,200 and 1,600 mg/kg/day, dams had ataxia and reductions in mean weight gain and food consumption. At the 1,600 mg/kg/day, pregnant rats had mean weight loss, and one female aborted prior to the end of the study. Maternal toxicity at these levels corresponds to decreased fetal body weights and gravid uterine weights. Additionally, at 1,600 mg/kg/day, there was one abortion and one whole litter resorption. However, the number of fetal malformations, such as increased incidence of skeletal variations (delayed ossification, extra ribs), was not significantly different from controls. A maternal NOAEL of 500 mg/kg/day was determined by the Agency, and the same NOAEL was determined in the study for fetal toxicity. These results support the results of a study described in this unit and indicate that 2-methyl-2,4-pentanediol has low potential for developmental toxicity.

2-methyl-2,4-pentanediol is not genotoxic in either mammalian or non-mammalian cells ''in vitro.'' It was negative for mutagenicity in the Ames test, yeast cell assay and hamster ovary cell assay.

Ten rats and a rabbit exposed to an aerosol of 2-methyl-2,4-pentanediol at a concentration of 0.7 mg/L (about 145 ppm) for 7 hr/day for 9 days survived with mild upper respiratory irritation. No histopathological effects were reported.

B. Toxicological Points of Departure/Levels of Concern

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

No acute endpoint of concern was identified in the available toxicity studies. The endpoint of concern for the

chronic reference dose (cRfD) was identified from the developmental toxicity study in rats. In this study, the NOAEL (500 mg/kg/day) was based on increased incidence of clinical signs, reductions in mean body weight gain and food consumption seen at the LOAEL of 1,200 mg/kg/day and above. This NOAEL was supported by the 90-day gavage toxicity study in rats (NOAEL 450 mg/kg/day; highest dose tested). There was a lower NOAEL (300 mg/kg/day) observed in the range finding study in rats based on a statistically significant reduction in group mean body weight gain and food consumption, and marginally higher incidences of fetal variations seen at the LOAEL of 1,000 mg/kg/day. The differences between the NOAELs of the range finding study and the developmental toxicity study in rats were considered due to artifacts of dose selection. An uncertainty factor 100X (10X for intraspecies variability and 10X interspecies extrapolation) was applied to the NOAEL. No additional uncertainty factor is necessary for use of the subchronic to chronic study because the effects were observed at the limit dose of 1,000 mg/kg/day and above. The FQPA factor for increased susceptibility of infant and children was reduced to 1X. Therefore, the cRfD is equal to population adjusted dose (cPAD). This endpoint and the dose was also used for dermal and inhalation exposure assessment for all exposure scenarios. Inhalation and dermal absorption was assumed to be 100%. This approach would provide a highly conservative estimate of risk via the dermal and inhalation routes of exposure.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR 2-METHYL-2,4-PENTANEDIOL FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	No acute endpoint of concern was identified in the available database.		
Chronic dietary (All populations) ..... Incidental oral short-term and intermediate term.	NOAEL = 500 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 500 mg/kg/day. cPAD = 500 mg/kg/day.	Developmental Toxicity Study—rats LOAEL = 1,200 mg/kg/day based on reduced body weights in maternal animals, reduced fetal body weights.
Dermal short and intermediate term	100% absorption via dermal and inhalation routes; LOC MOE..		
Inhalation short and intermediate term	100.		
Cancer (Oral, dermal, inhalation)	No evidence of carcinogenicity. SAR analysis negative for carcinogenic alerts. Not mutagenic in mammalian and non-mammalian mutagenicity assays.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 2-methyl-2,4-pentanediol, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 2-methyl-2,4-pentanediol in food as follows:

No acute endpoint of concern was identified in the database. Therefore, a quantitative acute dietary exposure assessment was not conducted.

i. *Chronic exposure.* In conducting the chronic dietary exposure assessments, EPA used food consumption information from the United States Department of Agriculture (USDA) [1994–1996 and 1998] Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for 2-methyl-2,4-pentanediol. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentration of active ingredient in agricultural products is generally at least 50% of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100% of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

ii. *Cancer.* Chronic and carcinogenicity studies were not available on 2-methyl-2,4-pentanediol. There is no evidence that 2-methyl-2,4-pentanediol is carcinogenic. The Agency used a qualitative structure activity relationship (SAR) database, DEREK Version 11, to determine if there were structural alerts. No structural alerts were identified. In addition, it is negative for mutagenicity in mammalian and non-mammalian mutagenicity assays. 2-methyl-2,4-pentanediol is rapidly metabolized and excreted as glucuronates. Based on weight-of-evidence and low toxicity mentioned in this unit, 2-methyl-2,4-pentanediol is not expected to be carcinogenic. Since the Agency has not identified any concerns for carcinogenicity relating to 2-methyl-2,4-pentanediol, a dietary exposure assessment to evaluate cancer risk was not performed.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for 2-methyl-2,4-pentanediol, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). No residential uses as a pesticide inert ingredient have been requested and none are expected. Although 2-methyl-2,4-pentanediol is used in cosmetics and hair care products, the Agency believes exposure and risk from these routes of exposure to be negligible. The FDA includes 2-methyl-2,4-pentanediol (*i.e.,* hexylene glycol) in its list of Indirect Additives Used in Food Contact Subtances. The exposure to 2-methyl-2,4-pentanediol through hair color use is considered minimal because it is a volatile chemical, treatment times are very short and absorption through the scalp is limited. Based on these considerations, the Agency concluded that there is no need to conduct aggregate exposure through use of consumer products. Further, there are no reliable data with which to estimate such exposures.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found 2-methyl-2,4-pentanediol to share a common mechanism of toxicity with any other substances, and 2-methyl-2,4-pentanediol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 2-methyl-2,4-pentanediol does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The maternal and developmental effects were only observed at the limit dose of 1,000 mg/kg/day and above in the developmental toxicity study in rats. Maternal and fetal toxicity were mainly manifested as decreases in body weights. Marginally higher incidences of fetal variations were also observed at the limit dose or above. There were no guideline reproduction studies available on 2-methyl-2,4-pentanediol; however, no adverse effects on reproductive organs (including testes, prostate, seminal vesicles, epididymis, ovaries, vagina, and uterus) were observed at doses up to 450 mg/kg/day in a 90-day toxicity study in rats. In addition, the reproductive indices were not affected in the two available developmental toxicity studies in rats.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for 2-methyl-2,4-pentanediol is not complete but considered as adequate for FQPA assessment given the low toxicity of 2-methyl-2,4-pentanediol. No guideline reproduction studies were available for assessment; however, no adverse effects on reproductive organs (including testes, prostate, seminal vesicles, epididymis, ovaries, vagina, and uterus) were observed in the 90-day gavage study in which rats were administered 2-methyl-2,4-pentanediol at doses up to 450 mg/kg/day. Therefore, OECD SIDS concluded that no additional studies are required under the SIDS program regarding fertility. EPA is in agreement

with the OECD conclusion. Chronic studies are also not available, but the concern for chronic toxicity is low given the low toxicity of 2-methyl-2,4-pentanediol.

ii. No evidence of clinical signs of neurotoxicity was observed in the available database. No evidence of neurobehavioral or neuropathology was seen in a 90-day toxicity study in rats. There is no indication that 2-methyl-2,4-pentanediol is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that 2-methyl-2,4-pentanediol results in increased susceptibility in rats (as described in this unit).

iv Immunotoxicity studies for 2-methyl-2,4-pentanediol were not available for review. However, there was no evidence of immunotoxicity in the available database.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 percent crop treated (PCT) and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to 2-methyl-2,4-pentanediol in drinking water. These assessments will not underestimate the exposure and risks posed by 2-methyl-2,4-pentanediol.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute (aPAD) and chronic (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, 2-methyl-2,4-pentanediol is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to 2-methyl-2,4-pentanediol from food and water will utilize 3.8% of the cPAD for the U.S. population and Children 1–2 yrs of age 12.5% cPAD, the population group receiving the greatest exposure. Based on the explanation in this unit, regarding residential use patterns, chronic residential exposure to residues of 2-methyl-2,4-pentanediol is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A short-term adverse effect was identified; however, 2-methyl-2,4-pentanediol is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure resulting from use as an inert ingredient in pesticidal formulations and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for 2-methyl-2,4-pentanediol.

For the reasons discussed in Unit IV.C.3., short-term aggregate exposure assessment was not conducted for non-pesticidal uses.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, 2-methyl-2,4-pentanediol is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for 2-methyl-2,4-pentanediol. For the reasons discussed in Unit IV.C.3., intermediate term aggregate exposure assessment was not conducted for non-pesticidal uses.

5. *Aggregate cancer risk for U.S. population.* 2-methyl-2,4-pentanediol is not expected to pose a cancer risk to humans. Therefore, aggregate cancer risk was not performed.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to 2-methyl-2,4-pentanediol residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for 2-methyl-2,4-pentanediol.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 and § 180.930 for 2-methyl-2,4-pentanediol. (CAS Reg. No. 107–1–41–5) when used as an inert ingredient in pesticide formulations applied to crops and food animals without limitations.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory*

Planning and Review (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 10, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.910 Insert ingredients used pre-harvest and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* * *	* * *
2-methyl-2,4-pentanediol (CAS Reg. No.–107–41–5)	Without limitation	Growing crops and food animals
* * *	* * *	* * *

■ 3. In § 180.930, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.930 Insert ingredients applied to animals: exemption from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* * *	* * *
2-methyl-2,4-pentanediol (CAS Reg. No.–107–41–5)	Without limitation	Growing crops and food animals
* * *	* * *	* * *

[FR Doc. 2011–15466 Filed 6–21–11; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0474; FRL–8877–1]

Diethylene Glycol MonoEthyl Ether (DEGEE); Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of Diethylene Glycol MonoEthyl Ether (DEGEE) when used as an inert ingredient as a solvent, stabilizer and/or antifreeze within pesticide formulations/products, for preharvest use on growing crops and raw agricultural commodities, without limitation. Huntsman, Dow AgroSciences L.L.C., Nufarm Americas Inc., BASF, Stepan Company, Loveland Products Inc., and Rhodia Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of DEGEE on growing crops and raw agricultural commodities.

DATES: This regulation is effective June 22, 2011. Objections and requests for hearings must be received on or before August 22, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0474. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Lisa Austin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 305–7894; *e-mail address: austin.lisa@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0474 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 22, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2008–0474, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Exemption

In the **Federal Register** of July 9, 2008 (73 FR 39291) (FRL–8371–2), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 8E7355) by Huntsman, 10003 Woodloch Forest Drive, The Woodlands, TX 77380; Dow AgroSciences L.L.C., 9330 Zionsville Road, Indianapolis, Indiana 46268; Nufarm Americas Inc., 150 Harvester Drive, Suite 220, Burr Ridge, Illinois, 60527; BASF, 26 Davis Drive, Research Triangle Park, NC 27709; Stepan Company, 22 W. Frontage Road, Northfield, IL 60093; Loveland Products Inc., PO Box 1286, Greeley, CO 80632; and Rhodia Inc., CN 1500, Cranbury, New Jersey, 08512. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of DEGEE (CAS Reg. No. 111–90–0) when used as an inert ingredient, as a solvent, stabilizer and/or antifreeze

in pesticide formulations applied to growing crops and raw agricultural commodities pre-harvest without limitation. That notice referenced a summary of the petition prepared by Huntsman, Dow AgroSciences L.L.C., Nufarm Americas Inc., BASF, Stepan Company, Loveland Products Inc., and Rhodia Inc., the petitioners, which is available in the docket, *http://www.regulations.gov.* The Agency received one comment in response to the notice of filing.

Currently, there is a tolerance exemption for DEGEE under 40 CFR 180.920 when it is used as a deactivator for formulations used before the crops emerge from the soil and stabilizer. This document provides an assessment of the risk to human health and the environment for DEGEE when used as a pesticide inert ingredient as a solvent, stabilizer and/or antifreeze within pesticide formulations/products without limitation.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. * * *''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by DEGEE as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The following toxicity data on DEGEE were summarized from these sources, the World Health Organization (WHO), National Toxicology Program (NTP), Hazardous Substances Data Base (HSDB) and BIBRA Toxicology Advisory and Consulting (1976, 2003, respectively). DEGEE has low acute toxicity via oral and dermal routes. It is moderately irritating to the skin and is mildly irritating to the eye. It is not a skin sensitizer.

Several subchronic studies with DEGEE were available in rodents, ferrets and pigs. In rodents, toxicity was primarily manifested in the kidneys and liver. Increased kidney weights, tubular dilatation and centrilobular hepatocyte enlargement were seen at doses > 2,500 milligrams/kilogram/day (mg/kg/day). In ferrets, effects in the kidney were also observed. The concentrating power of the kidney was decreased and water intake was decreased at > 2.0 milliliter (mL)/kg/day (2,240 mg/kg/day). Kidney and liver effects were also observed in pigs. Kidney weights were increased, tubular hydropic degeneration and enlarged centrilobular and midzonal hepatocytes with pyknotic nuclei and fatty infiltration were observed at > 500 mg/kg/day.

A subchronic inhalation study with DEGEE in the rat was also available. No effects were observed at doses up to 1.1 milligrams/liter (mg/L) (approximately 314 mg/kg/day).

Several chronic carcinogenicity studies with DEGEE were available in rodents. However, these studies were conducted with a limited number of animals and doses and a complete histopathological examination was not performed. Due to these deficiencies, a definitive conclusion regarding carcinogenicity of DEGEE cannot be made on the basis of these studies. However, there were no obvious tumors detected in mice and rats.

Developmental studies with DEGEE in rodents were available for review. Fetal susceptibility was not observed in these studies. Parental (mortality and reduced body weight) and offspring (reduced mean pup birth weight) toxicity were observed in mice at the high dose (2,500 mg/kg/day). In a developmental toxicity study in rats via the dermal route of exposure, maternal toxicity was manifested as decreased body weight at 6,615 mg/kg/day. Developmental toxicity was not observed at this dose. In an inhalation developmental toxicity study in rats, maternal and developmental toxicity were not observed up to 100 parts per million (ppm) (approximately 31 mg/kg/day).

Two reproduction toxicity studies were available for review with DEGEE in rodents. One study in rats reported that increased urinary protein, bladder calculi, epithelial necrosis of the renal

tubules and cloudy swelling of hepatic tissue were observed in all animals at 920 mg/kg/day of DEGEE with less than 0.2% of ethylene glycol. The NOAEL in this study was 200 mg/kg/day. In another study in mice, offspring toxicity (decreased live pup weights, decreased absolute brain and liver weights) and parental toxicity (increase water intake and decreased body weight in males) occurred at 2,500 mg/kg/day. There were no effects on reproductive parameters in either study.

Several mutagenicity studies (Ames test, micronucleus assay and unscheduled DNA synthesis) with DEGEE were available for review. One Ames test reported ambiguous results, another reported positive results at high doses. However, *in vivo* assays (micronucleus and unscheduled DNA synthesis) reported negative results. Therefore, based on the weight of evidence, DEGEE is not considered mutagenic.

As noted, available long-term carcinogenicity studies were considered inadequate to fully assess DEGEE's potential to cause cancer; however, these studies in mice and rats do not report any tumors. DEGEE belongs to the glycol ether class of chemicals which include structurally similar chemicals ethylene glycol (EG) and diethylene glycol (DEG). EG and DEG have toxicities similar to DEGEE. Target organs of toxicity are the kidney and liver. There was no evidence of carcinogenicity in rats and mice when treated with EG (NTP). Bladder tumors were observed in rats treated with DEG at >1,500 mg/kg/day, however, these tumors were secondary to irritation from bladder stones. The resulting classification for EG and DEG was that they are not expected to pose a carcinogenic risk in humans. Therefore, the carcinogenicity data on EG and DEG were used to assess the cancer potential of DEGEE. Based on the lack of evidence of carcinogenicity potential for EG and DEG, lack of tumors in mice and rats with DEGEE, and the fact that DEGEE is not mutagenic, DEGEE is not expected to be carcinogenic to humans. Also, the established chronic reference dose/chronic population adjusted dose (cRfD/cPAD) (2.0 mg/kg/day) for DEGEE will be protective of effects leading to kidney damage and tumor formation seen at >1,500 mg/kg/day following DEG exposures.

Immunotoxicity studies for DEGEE were not available for review. However, DEGEE belongs to the glycol ethers class of chemicals. Immunotoxicity studies were available for ethylene glycol mono butyl ether (DEGBE), also a glycol ether differing in only one ethyl and butyl group from DEGEE. These data were used to assess the immunotoxic potential of DEGEE. Signs of potential immunotoxicity were not observed in any of the available studies for the surrogate chemical. Nor was there evidence of immunotoxicity potential in any of the studies submitted for DEGEE. Therefore, DEGEE is not expected to be immunotoxic.

Dermal absorption studies were available with DEGEE. In a study using human epidermal membranes, the absorption rate of DEGEE was 0.206 mg/cm^2/hr.

The available metabolism data in an adult human revealed that 68% of the administered dose of DEGEE was excreted in the urine as (2-ethoxy) acetic acid. In a metabolism study in the rabbit, oral or subcutaneous exposure to DEGEE resulted in the excretion of glucuronic acid in the urine; the major part of the dose was oxidized.

B. Toxicological Points of Departure/Levels of Concern

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

A summary of the toxicological endpoints for DEGEE used for human risk assessment is shown in the following table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR DEGEE FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary general population including Females 13–50 years of age.	An acute endpoint was not identified in the database.		
Chronic dietary (All populations)	NOAEL = 200 mg/kg/day ..... UF_A = 10x UF_H = 10 x FQPA SF = 1x	Chronic RfD = 2.0 mg/kg/day cPAD = 2.0 mg/kg/day.	Reproduction Toxicity Study with chronic/ carcinogenicity measurements—rat LOAEL = 920 mg/kg bw/day, based on decreased growth, epithelial necrosis of renal tubules and cloudy swelling of hepatic tissue.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR DEGEE FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Incidental oral short-term (1 to 30 days).	NOAEL= 200 mg/kg/day ..... UF_A = 10x UF_H = 10 x FQPA SF = 1x	LOC for MOE = 100	Reproduction Toxicity Study with chronic/carcinogenicity measurements—rat LOAEL = 920 mg/kg bw/day, based on decreased growth, epithelial necrosis of renal tubules and cloudy swelling of hepatic tissue.
Incidental oral intermediate-term (1 to 6 months).	NOAEL= 200 mg/kg/day ..... UF_A = 10x UF_H = 10 x FQPA SF = 1x	LOC for MOE = 100	Reproduction Toxicity Study with chronic/carcinogenicity measurements—rat LOAEL = 920 mg/kg bw/day, based on decreased growth, epithelial necrosis of renal tubules and cloudy swelling of hepatic tissue.
Dermal short-term (1 to 30 days) ..	NOAEL= 200 mg/kg/day (dermal absorption rate = 25%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Reproduction Toxicity Study with chronic/carcinogenicity measurements—rat LOAEL = 920 mg/kg bw/day, based on decreased growth, epithelial necrosis of renal tubules and cloudy swelling of hepatic tissue.
Dermal intermediate-term (1 to 6 months).	NOAEL= 200 mg/kg/day (dermal absorption rate = 25% when appropriate). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Reproduction Toxicity Study with chronic/carcinogenicity measurements—rat LOAEL = 920 mg/kg bw/day, based on decreased growth, epithelial necrosis of renal tubules and cloudy swelling of hepatic tissue.
Inhalation short-term (1 to 30 days).	Inhalation (or oral) study NOAEL= 200 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Reproduction Toxicity Study with chronic/carcinogenicity measurements—rat LOAEL = 920 mg/kg bw/day, based on decreased growth, epithelial necrosis of renal tubules and cloudy swelling of hepatic tissue.
Inhalation (1 to 6 months)	Inhalation (or oral) study NOAEL = 200 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Reproduction Toxicity Study with chronic/carcinogenicity measurements—rat LOAEL = 920 mg/kg bw/day, based on decreased growth, epithelial necrosis of renal tubules and cloudy swelling of hepatic tissue.
Cancer (Oral, dermal, inhalation) ..	Based on the lack of tumors in a study with DEGEE and carcinogenicity data available for the structurally similar chemicals, EG and DEG, and that DEGEE is not mutagenic, DEGEE is not expected to be carcinogenic to humans.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to DEGEE, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from DEGEE in food as follows:

i. *Acute exposure.* No adverse effects attributable to a single exposure of DEGEE were seen in the toxicity databases. Therefore, an acute dietary exposure assessment for DEGEE is not necessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used food consumption information from the U.S.

Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for DEGEE. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts,'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest levels of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

iii. *Cancer.* As discussed above, the Agency has not identified any concerns for carcinogenicity relating to DEGEE, and, therefore, a dietary exposure assessment to assess cancer risk is unnecessary.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for DEGEE, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

DEGEE may be used in inert ingredients in products that are registered for specific uses that may result in residential exposure. A screening level residential exposure and risk assessment was completed for products containing DEGEE as inert ingredients. The Agency selected representative scenarios, based on end-use product application methods and labeled application rates. The Agency conducted an assessment to represent worst-case residential exposure by assessing DEGEE in pesticide formulations (Outdoor Scenarios) and DEGEE in disinfectant-type uses (Indoor Scenarios). The Agency is not aware of any use of DEGEE in hard surface cleaning products. However, this scenario was used for this assessment considering wide use of DEGEE in other products. Therefore, the Agency assessed the disinfectant-type products containing DEGEE using exposure scenarios used by the Antimicrobials Division in EPA's Office of Pesticide Programs to represent worst-case residential handler exposure. Further details of this residential exposure and risk analysis can be found at *http://www.regulations.gov* in the memorandum entitled: ''JITF Inert Ingredients. Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations,'' (D364751, 5/7/09, Lloyd/LaMay in docket ID number EPA–HQ–OPP–2008–0710.

In addition to pesticidal uses for DEGEE, there are non-pesticidal uses for DEGEE. However, dermal and inhalation exposure are expected to be negligible; therefore, a quantitative exposure assessment was not conducted.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found DEGEE to share a common mechanism of toxicity with any other substances, and DEGEE does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that DEGEE does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to

evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Fetal susceptibility was not observed in the developmental toxicity studies with DEGEE in the mouse. Developmental studies were available via the oral (mice), dermal (rats) and inhalation (rats) routes of exposure in rodents. Following oral exposure to DEGEE, maternal (mortality and reduced body weight) and offspring (reduced mean pup birth weight) toxicity were observed in mice at the high dose (2,500 mg/kg/day). Following dermal exposure to DEGEE, maternal toxicity was manifested as decreased body weight at 6,615 mg/kg/day in rats. Developmental toxicity was not observed at this dose. Following inhalation exposure to DEGEE, maternal and developmental toxicity were not observed up to 100 ppm (approximately 31 mg/kg/day) in rats. A developmental toxicity study in rabbits is not available in the database. However, the concern for the lack of this study is low because toxicity was observed near the limit dose in the developmental and reproduction studies in rodents (>920 mg/kg/day).

Evidence of increased fetal susceptibility was observed in a reproduction toxicity study in the mice. Offspring toxicity was manifested as decreased adjusted live pup weight and absolute brain weights and increased liver weights in the absence of parental toxicity. There is no concern for this increased susceptibility in mice because these pup effects were observed at a dose 2.5 times above the limit dose of 1,000 mg/kg/day and a clear NOAEL was established in the study. It is unclear if there is fetal susceptibility in the reproduction toxicity study in rats. In this study, it was stated that increased urinary protein, bladder calculi, epithelial necrosis of the renal tubules and cloudy swelling of hepatic tissue were observed in all animals at 920 mg/kg/day (NOAEL 200 mg/kg/day). It is not clear whether all animals referred in the study include both the parental and F1 animals or not. However, in any case the concern for fetal susceptibility is low because the aforementioned effects occured near the limit dose and the cRfD (2.0 mg/kg/day) will be protective of these effects.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for DEGEE is adequate for FQPA assessment. The following acceptable studies are available: Developmental and reproduction toxicity studies in mice and rats, subchronic and mutagenicity studies. A 2-generation reproduction toxicity study where tumors were evaluated is available. Also, chronic/carcinogenicity studies are available on a surrogate chemical, ethylene glycol. A developmental toxicity study in rabbits is not available in the database. However, the concern for the lack of this study is low because toxicity was observed at or above the limit dose in the developmental and reproduction studies in rodents.

ii. Signs of neurotoxicity were not observed in a reproduction toxicity study in rats. Decreased absolute brain weights were observed in the offspring at 2,500 mg/kg/day. However, a developmental neurotoxicity study is not required because decreased brain weights were observed above the limit dose (1,000 mg/kg/day), the effect occurred in the presence of maternal toxicity and the cRfD (2.0 mg/kg/day) will be protective of this effect. Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is evidence that DEGEE results in increased fetal susceptibility in the multi-generation reproduction study in the mouse. However, the concern for fetal susceptibility is low because the effects seen in the offspring (adjusted live pup weight and absolute brain weights and increased liver weights) occur at 2,500 mg/kg/day (2.5times the limit dose), the effects occur in the absence of maternal toxicity, a clear NOAEL (1,250 mg/kg/day) was established and the cRfD (2.0 mg/kg/day) will be protective of these effects.

iv. Immunotoxicity studies for DEGEE were not available for review. However, DEGEE belongs to the glycol ethers class of chemicals. Immunotoxicity studies were available for ethylene glycol monobutyl ether, also a glycol ether. This data were used to assess the immunotoxic potential of DEGEE. Signs of potential immunotoxicity were not observed in any of the available studies for the surrogate chemical. Nor was there evidence of immunotoxicity potential in any of the studies submitted for DEGEE. Therefore, DEGEE is not expected to be immunotoxic.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated (CT) and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to DEGEE in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by DEGEE.

E. Aggregate Risks and Determination of Safety

Determination of safety section. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, DEGEE is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to DEGEE from food and water will utilize 0.10% of the cPAD for the general U.S. population and 0.31% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in this unit, regarding residential use patterns, chronic residential exposure to residues of DEGEE is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

DEGEE is currently used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to DEGEE.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 264 for both adult males and females, respectively. Adult residential exposure combines high end dermal and inhalation handler exposure from homeowner mixer/loader/applicators using a trigger sprayer with a high end post application dermal exposure from contact with treated lawns. As the level of concern is for MOEs that are lower than 100, this MOE is not of concern. EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 228 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). Because EPA's level of concern for DEGEE is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

DEGEE is currently used as an inert ingredient in pesticide products that are registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to DEGEE.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 777 for adult males and females. Adult residential exposure combines high end dermal and inhalation handler exposure from homeowner mixer/loader/applicators using a trigger sprayer with a high end post application dermal exposure from contact with treated lawns. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 267 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). Because EPA's level of concern for DEGEE is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* DEGEE is not expected to pose a carcinogenic risk in humans based on the discussion in Unit IV.A.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to DEGEE residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for DEGEE.

C. Response to Comments

The comment was received from private citizens who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for DEGEE (CAS Reg. No. 111–90–0) when used as an inert ingredient (as a solvent, stabilizer and/or antifreeze within pesticide formulations/products without limitation) in pesticide formulations applied to growing crops and raw agricultural commodities pre-harvest.

VII. Statutory and Executive Order Reviews

This final rule establishes an exemption from tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such,

the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 10, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.920, the table is amended by adding alphabetically the following inert ingredient:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* * *
Diethylene Glycol MonoEthyl Ether (CAS Reg. No. 111–90–0).	Without limitation	Solvent, stabilizer and/or antifreeze.
* * *	* *	* * *

[FR Doc. 2011–15266 Filed 6–21–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0517; FRL–8876–2]

C_9 Rich Aromatic Hydrocarbons, $C_{10–11}$ Rich Aromatic Hydrocarbons, and $C_{11–12}$ Rich Aromatic Hydrocarbons; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of C_9 rich aromatic hydrocarbons; $C_{10–11}$ rich aromatic hydrocarbons; and $C_{11–12}$ rich aromatic hydrocarbons, when used as inert ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. ExxonMobil Chemical Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons.

DATES: This regulation is effective June 22, 2011. Objections and requests for hearings must be received on or before August 22, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2011–0517. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kerry Leifer, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 308–8811; *e-mail address: leifer.kerry@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2011–0517 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 22, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0517, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Exemption

In the **Federal Register** of January 25, 2006 (71 FR 4135) (FRL–7750–4) for C_9 rich aromatic hydrocarbons, January 23, 2006 (71 FR 3512) (FRL–7750–3) for C_{10-11} rich aromatic hydrocarbons, and February 1, 2006 (71 FR 5321) (FRL–7750–5) for C_{11-12} rich aromatic hydrocarbons, EPA issued notices pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of pesticide petitions (PP 5E6935, 5E6934, and 4E6937 respectively) by ExxonMobil Chemical Company, 13501 Katy Freeway, Houston, TX 77079. The petitions requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of C_9 rich aromatic hydrocarbons (CAS Reg. No. 64742–95–6), C_{10-11} rich aromatic hydrocarbons (CAS Reg. No. 64742–94–5), and C_{11-12} rich aromatic hydrocarbons (CAS Reg. No. 64742–94–5) when used as inert ingredients (solvents) in pesticide formulations applied to raw agricultural commodities and growing crops under 40 CFR 180.910. Those notices referenced summaries of the petitions prepared by ExxonMobil, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notices of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has

reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons follows.

A. Toxicological Profile

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

C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons are products of the petroleum distillation and refining process. These substances are various fractions of aromatic petroleum hydrocarbons with specific boiling point ranges and flash points. Each of the substances is comprised of a complex mixture of aromatic hydrocarbon molecules in the range of 9 to 12 carbon atoms. Since C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons differ only in the proportions of the various hydrocarbon molecules within the C_9 to C_{12} range, they have similar physicochemical and toxicological properties and have therefore been assessed together.

C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons exhibit low acute toxicity by oral, inhalation and dermal routes (toxicity Category III or IV by all exposure routes). They are minimally irritating to eyes and skin and negative for dermal sensitization effects. Subchronic oral and inhalation toxicity studies indicate these substances to be relatively non-toxic. Reversible effects to the liver, thyroid, stomach, spleen, and urinary bladder were reported at mid and high doses in a subchronic oral toxicity study in rats. A developmental inhalation study in mice indicates no evidence of developmental effects or any adverse effects in maternal animals at dose levels below 715 milligrams/kilogram/day (mg/kg/day). An oral developmental study in rats indicates maternal effects (decreased body weight gain and food consumption) at the mid-dose (150 mg/kg/day) but no developmental effects at the highest dose tested (450 mg/kg/day). An inhalation reproduction study in rats indicates reduced body weight gain in parents and offspring at mid and high doses (715 and 2,145 mg/kg/day). Based on neurotoxicity studies, C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons are not expected to cause any nervous system damage. Due to their complex, multi-constituent nature, there are no substance-specific absorption, metabolism, distribution and excretion studies done specifically on C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons. However, sufficient metabolism data are available on other aromatic hydrocarbons to show that as a class they are typically well-absorbed, widely distributed between tissues, extensively metabolized and rapidly excreted. C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons are of low toxicological concern for developmental and reproductive effects, based on the available toxicity data, and are not expected to be carcinogenic.

Specific information on the studies received and the nature of the adverse effects caused by C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document ''Exemptions From the Requirement of a Tolerance for C9 Rich Aromatic Hydrocarbons, C10–11 Rich Aromatic Hydrocarbons, C11–12 Rich Aromatic Hydrocarbons,'' at pp 5–17 in docket ID number EPA–HQ–OPP–2006–0517.

B. Toxicological Points of Departure/Levels of Concern

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

A summary of the toxicological endpoints for C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons used for human risk assessment is shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR C_9, $C_{10–11}$, AND $C_{11–12}$ RICH AROMATIC HYDROCARBONS FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations)	NOAEL = 150 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 1.5 mg/kg/day ..... aPAD = 1.5 mg/kg/day	OCSPP Harmonized Test Guideline 870.3700 Prenatal Developmental Toxicity Study in Rats Maternal LOAEL = 450 mg/kg/day based on decreased body weight gain and decreased food consumption.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR C_9, C_{10-11}, AND C_{11-12} RICH AROMATIC HYDROCARBONS FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Chronic dietary (All populations)	NOAEL= 150 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 1.5 mg/kg/day ..... cPAD = 1.5 mg/kg/day	OCSPP Harmonized Test Guideline 870.3700 Prenatal Developmental Toxicity Study in Rats Maternal LOAEL = 450 mg/kg/day based on decreased body weight gain and decreased food consumption
Cancer (Oral, dermal, inhalation) ..	Based on structure-activity relationship (SAR) analysis and structural alerts, not expected to be carcinogenic.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. LOC=level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons in food as follows:

i. *Acute exposure.* In conducting the acute dietary exposure assessment for C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons, EPA used food consumption information from the U.S. Department of Agriculture (USDA) [1994–1996 and 1998] Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredients. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data can be found at *http://www.regulations.gov* in the document ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts,'' in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product relative to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level, *i.e.,* EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, and then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment for C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound chronic dietary exposure estimates for the subject inert ingredient. This

approach is as described in Unit IV. C.1.i.

iii. *Cancer.* The Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts for carcinogenicity were identified. Therefore, a cancer dietary exposure assessment is not necessary to assess cancer risk.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons are not currently used as inert ingredients in pesticide products that are registered for any use patterns that involve residential uses nor are there any other non-pesticidal residential uses for these inert ingredients, thus no residential exposures to C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons are expected. The primary non-pesticidal uses of C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons are as gasoline additives. Residential exposures to these substances as a result of their use as gasoline additives could occur via inhalation during refueling and from potential transport of gasoline containing C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons into groundwater. There are no reliable data upon which to quantitatively assess such exposures to C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons; however, modeled data for other gasoline additives suggest that inhalation exposures would be at levels of <5 micrograms/kilogram/day, and that levels in groundwater would not exceed 0.2–16 ppb.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.

EPA has not found C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons to share a common mechanism of toxicity with any other substances, and C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10×) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10×, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The available mammalian toxicology database for C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons is complete with respect to assessing increased susceptibility to infants and children. There were no adverse effects on the offspring of rats following prenatal and postnatal exposure in the OCSPP Harmonized Test Guideline 870.3700 oral developmental toxicity study at the highest dose tested of 450 mg/kg/day. In a 3-generation inhalation toxicity study in rats, reproductive effects were seen only at dose levels above that at which parental effects were noted.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1×. That decision is based on the following findings:

i. The toxicity database for C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons is largely complete, missing only a developmental neurotoxicity study and an immunotoxicity study. EPA has determined that an additional uncertainty factor is not needed to account for the lack of these studies for the following reasons:

- There were no neurotoxic effects observed at the highest dose tested in a 90-day inhalation neurotoxicity study in rats with a C_9 aromatic hydrocarbon material. There is no evidence that C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons are neurotoxic chemicals and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- There is no evidence that C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons result in increased susceptibility in *in utero* rats in the prenatal developmental studies or in young rats in a 3-generation reproduction study.
- An immunotoxicity study is not available; however, there is no evidence of immune system involvement in the available toxicity database for C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons, therefore, there is no need to add additional UFs to account for the lack of an immunotoxicity study.

ii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 percent crop treated (PCT) and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons in drinking water. These assessments will not underestimate the exposure and risks posed by C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich

aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons will occupy 2.8% of the aPAD for children (1 to 2 years old), the population group receiving the greatest exposure. Therefore, C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons are not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons from food and water will utilize 0.6% of the cPAD for children (1 to 2 years old), the population group receiving the greatest exposure. There are no residential pesticide uses for C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons. As noted in Unit IV.C.3., non-pesticidal drinking water exposure to C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons may be possible from potential transport of gasoline containing C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons into groundwater; however, those potential exposures are addressed by the use of a conservative drinking water concentration value of 100 ppb used to assess the contribution to drinking water for the chronic dietary risk assessments, therefore no further assessment of this potential exposure is needed.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons are not currently used as inert ingredients in pesticide products that are registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons. As noted in Unit IV.C.3., there may be short-term inhalation exposures to C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons when these substance are present as gasoline additives during gasoline refueling, however those exposures would be expected to be at levels at least three orders of magnitude below any level of concern and therefore have not been included in a quantitative short-term risk assessment.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons are not currently used as inert ingredients in pesticide products that are registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons.

5. *Aggregate cancer risk for U.S. population.* The Agency has not identified any concerns for carcinogenicity relating to C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons and C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons are not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180. 910 for residues of C_9 rich aromatic hydrocarbons (CAS Reg. No. 64742–95–6), C_{10-11} rich aromatic hydrocarbons (CAS Reg. No. 64742–94–5), and C_{11-12} rich aromatic hydrocarbons (CAS Reg. No. 64742–94–

5) when used as inert ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.

VII. Statutory and Executive Order Reviews

This final rule establishes exemptions from tolerance under section 408(d) of FFDCA in response to petitions submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 10, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910 the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * * *		*
C_9 rich aromatic hydrocarbons (CAS Reg. No. 64742–95–6)		Solvent.
* * * * * *		*
$C_{10–11}$ rich aromatic hydrocarbons (CAS Reg. No. 64742–94–5)		Solvent.
* * * * * *		*
$C_{11–12}$ rich aromatic hydrocarbons (CAS Reg. No. 64742–94–5)		Solvent.
* * * * * *		*

[FR Doc. 2011–15269 Filed 6–21–11; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 262

[EPA–HQ–RCRA–2001–0032; FRL–9321–8]

Hazardous Waste Manifest Printing Specifications Correction Rule

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking Direct Final action on a minor change to the Resource Conservation and Recovery Act (RCRA) hazardous waste manifest regulations that affects those entities that print the hazardous waste manifest form in accordance with EPA's Federal printing specifications. Specifically, this action amends the current printing specification regulation to indicate that red ink, as well as other distinct colors, or other methods to distinguish the copy distribution notations from the rest of the printed form and data entries are permissible. This change will afford authorized manifest form printers greater flexibility in complying with the Federal printing specifications.

DATES: This Direct Final Rule is effective on August 22, 2011 without further notice unless EPA receives adverse comments by July 22, 2011. If an adverse comment is received, EPA will publish a timely withdrawal of the Direct Final Rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments identified by Docket ID No. EPA–HQ–RCRA–2001–0032 by one of the following methods:

- *http://www.regulations.gov:* follow the on-line instructions for submitting comments.
- *E-mail: RCRA_docket@EPA.gov* and *groce.bryan@epa.gov* or *lashier.rich@epa.gov.* Attention Docket ID No. EPA–HQ–RCRA–2001–0032
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–RCRA–2001–0032.
- *Mail:* RCRA Docket (28221T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Attention Docket ID No. EPA–HQ–RCRA–2001–0032. Please include a total of two copies of your comments.
- *Hand Delivery:* Please deliver two copies to the EPA Docket Center, EPA West Building, Room 3334, 1301 Connecticut Ave., NW., Washington DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–RCRA 2001–0032. EPA's policy is that all comments received will be included in the public docket without change and be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are within 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 HQ–Docket Center, Docket ID No. EPA–HQ–RCRA 2001–0032, EPA West Building, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the RCRA Docket is (202) 566–0270. A reasonable fee may be charged for copying docket materials.

FOR FURTHER INFORMATION CONTACT: For more information on this rulemaking, contact Bryan Groce or Richard LaShier, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (MC: 5304P), 1200 Pennsylvania Ave., NW., Washington, DC 20460; Phone for Bryan Groce: (703) 308–8750, Phone for Richard LaShier: (703) 308–8796; or e-mail: *groce.bryan@epa.gov,* or *lashier.rich@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Why is EPA using a direct final rule?

EPA is publishing this rule without prior proposal because we view this as a non-controversial action and anticipate no adverse comment. However, in the ''Proposed Rules'' section of today's **Federal Register** publication, we are publishing a separate document that will serve as the proposed rule to adopt the provisions in this Direct Final rule if adverse comments are filed. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. If we receive one or more adverse comments on this correction, we will publish a timely withdrawal in the **Federal Register** to notify the public that the amendment in this Direct Final rule that will not take effect. For further information about commenting on this rule, see the **ADDRESSES** section of this document.

II. Does this action apply to me?

Entities potentially affected by this action are the hazardous waste manifest printers subject to 40 CFR 262.21(f) of the RCRA hazardous waste regulations. States are not affected by the changes to the printing specifications unless they opt to print manifests. No states are currently printing these forms.

III. What should I consider as I prepare my comments for EPA?

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

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—the Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

- Explain why you disagree, suggests 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. Make sure to submit your comments by the comment period deadline identified.

IV. Acronyms

CFR United States Code of Federal Regulations
EPA United States Environmental Protection Agency
OMB Office of Management and Budget
RCRA Resource Conservation and Recovery Act
USC United States Code

V. Preamble

A. What is the legal authority for this direct final rule?

This rule is authorized under Sections 1004 and 3002 of the Resource Conservation and Recovery Act (RCRA) of 1976, as amended, 42 U.S.C. 6903 and 6922.

B. How does this direct final rule revise the federal printing specification regulations established in the March 2005 manifest revisions final rule?

Today's action amends 40 CFR 262.21(f)(4) in order to revise the regulatory language that currently requires that the manifest copy distribution notations (printed in the bottom right-hand corner of each page of the manifest) be printed only in red ink. EPA is amending this paragraph by revising it to read: ''The manifest and continuation sheet must be printed in black ink that can be legibly photocopied, scanned, or faxed, except that the marginal words indicating copy distribution must be printed with a distinct ink color or with another method (*e.g.,* white text against black background in a text box, or, black text against grey background in a text box) that clearly distinguishes the copy distribution notations from the other text and data entries on the form.'' This is the only manifest printing specification that we are revising in this Direct Final rule.

C. Why are we amending 40 CFR 262.21(f)(4)?

EPA adopted a nationally standardized manifest form during the promulgation of the March 4, 2005 Manifest Form Revisions Rule (70 FR 10776 *et seq.*) in order to replace the various State manifest forms that were previously distributed to users by the RCRA authorized States. The March 2005 rule also established the Manifest Registry system to ensure that authorized printers: (1) Produced the manifest form and continuation sheet with unique manifest tracking numbers pre-printed on them; and (2) adhered to the prescribed Federal printing specifications. The Manifest Revisions Rule generally required in 40 CFR 262.21(f)(4) that the manifest form be printed in black ink, except that certain marginal notations identifying the copy distribution requirements must be printed in red ink on all six copies of the multi-paged form. EPA specified the red ink requirement for the copy distribution notations was based on comments received on the May 2001 proposed rule notice. That is, while a number of commenters agreed that manifest printers should use black ink to print the form, several commenters suggested that the marginal notations should appear in red ink, because that ink color would help call attention to the copy distribution requirements and distinguish them from the remainder of the printed form entries.

While the red ink requirement for the copy distribution notations seemed sensible when we promulgated the final rule in 2005, EPA now believes that the red ink requirement is too prescriptive, and may prevent printers from utilizing new printing processes and methods. For example, EPA recently received an application from a hazardous waste management company that wished to print its own manifest forms using laser printers mounted on its transport vehicles. While the applicant was able to comply with nearly all of the Manifest Registry application requirements and printing specifications prescribed in § 262.21(f), the applicant could not easily comply with the aforementioned red ink requirement, while printing and assembling manifests on its transport vehicles. This difficulty resulted because the laser printers proposed for use in this mobile application could not produce red print. The applicant demonstrated with this application, however, that it could easily implement a highlighting method that had the desired effect of setting off the copy distribution notations from the other printed entries on the form. This application provided a good example of how the requirement in § 262.21(f) for red ink was unnecessarily prescriptive, and that an amendment would make sense. EPA believes that today's amendment will allow manifest printers greater flexibility in complying with the printing specifications, without incurring any additional costs or compromising in any way the ability of the manifest forms to track hazardous waste shipments cradle-to-grave. EPA believes that this is a very minor and non-controversial change to the printing specifications, and therefore is an appropriate subject for a Direct Final rule.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

OMB has determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011). Accordingly, EPA did not submit this action to OMB for review.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. This action provides additional flexibility to printers of the hazardous waste manifest by giving these printers additional options for printing in the margins of the manifest the copy distribution requirements for the form. While this action provides the printers with

additional flexibility when printing the manifest form, it will impose no new information collection burdens on the generators, transporters, or treatment, storage, disposal, or recycling facilities that are required to use the manifest to track shipments of hazardous waste.

OMB has previously approved the information collection requirements contained in the existing manifest regulations at 40 CFR part 262, subpart B, under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2050–0039. A copy of the OMB approved Information Collection Request (ICR) may be obtained from the Collection Strategies Division, U.S. EPA (2822T), 1200 Pennsylvania Ave., NW., Washington, DC 20460 or by calling (202) 566–1672.

Burden is defined at 5 CFR 1320.3(b). An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

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

After considering the economic impacts of today's Direct Final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This rule consists only of a minor technical change to the manifest printing specifications, and the effect of this change is to make it easier for printers to comply with the manifest printing specification by providing additional options. Therefore, this rule does not impose any new burden or costs on printers or users of the manifest, including printers and users who are small entities as defined by the RFA. Since the rule will not have any significant adverse economic impact on small entities, the RFA does not require EPA to perform a regulatory flexibility analysis.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or Tribal governments or the private sector.

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

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

This action does not contain any ''Federal intergovernmental mandates'' or any ''Federal private sector mandates'' subject to Title II of the UMRA. This Direct Final rule simply makes a minor change that allows hazardous waste manifest printers more flexibility in meeting the printing specifications for the hazardous waste manifest form. The Manifest Registry program under which printers may register to print the hazardous waste manifest is a voluntary Federal program. Currently, there are no states, local governments, or Tribal governments involved with printing the manifest, but even if such a governmental agency elected to print the manifest, it would do so by participating in the voluntary Manifest Registry Program. The UMRA generally excludes from the definition of ''Federal intergovernmental mandate'' and the definition of ''Federal private sector mandate'' those duties that arise from participation in a voluntary Federal program. Since all participants in the Manifest Registry for printers do so voluntarily, this action is not subject to the requirements of sections 202 or 205 of the UMRA. This action is also not subject to the requirements of section 203 of the UMRA, because it contains no regulatory requirements that might significantly or uniquely affect small governments. This action only affects hazardous waste manifest printers, and there are no small governments involved with printing the manifest. Thus, small governments are not significantly or uniquely affected by this action.

E. Executive Order 13132: Federalism

This action does not have Federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This action is only a minor regulatory change affecting the specifications under which hazardous waste manifest printers must print the manifest form. It does not impose substantial direct compliance costs. While the Federal printing specifications for manifest printers preclude States from requiring a different manifest form or different printing specifications, this preemptive effect arises under the RCRA consistency requirement for the manifest at 40 CFR 271.4 and from the uniformity requirements for the use of shipping papers under the Department of Transportation's Hazardous Materials transportation laws. The requirement for consistency and uniformity in the manifest, including the manifest printing specifications, was explained

in the Manifest Revisions Rule that EPA published in the March 4, 2005 **Federal Register** (70 FR 10776). The minor change to the printing specifications announced in today's rule will provide some additional flexibility for manifest printers to print the copy distribution notations on the form.

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

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249), requires EPA to develop a process to ensure ''meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications,'' as specified in Executive Order 13175. It will neither impose substantial direct compliance costs on Tribal governments, nor preempt Tribal law. This action has no effect on Tribal governments, as it only makes a minor change to the printing specifications that affect only entities printing the hazardous waste manifest. No Indian Tribes are involved with the printing of the hazardous waste manifest; nor are there any Indian Tribes with authorized Hazardous Waste regulatory programs that might have their own printing specifications for the hazardous waste manifest. Thus, Executive Order 13175 does not apply to this action.

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997). This action is not economically significant within the meaning of Executive Order 12866. Further, the action amends an administrative requirement pertaining to the manifest form, so it does not give rise to any environmental health or safety risks that could disproportionately affect children.

H. Executive Order 13045: Actions That Significantly Affect Energy Supply, Distribution, or Use

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

I. National Technology Advancement Act

Section 12(d) of the National Technology and Advancement Act of 1995 (NTTAA), Public Law No. 104—113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* material specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through the OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action amends the hazardous waste manifest printing specifications which are developed and maintained solely by EPA. When EPA initially published the manifest printing specifications in March 2005, there were no potentially applicable voluntary consensus standards for manifest printers. EPA decided to develop the current printing specifications, which now prescribe the standards applicable to manifest printers. With this action, EPA is retaining and amending the Federal standards developed in the 2005 Manifest Revisions Rule.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. EPA has determined that this Direct Final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because this rule simply makes a minor change to the hazardous waste manifest printing specifications. No minority or low-income population will be affected by this change.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et. seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other information required by the Congressional Review Act to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. Under this Act, a major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This Direct Final rule will be effective on August 22, 2011, unless EPA receives an adverse comment by July 22, 2011 and thereafter withdraws this direct final action.

List of Subjects in 40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

Dated: June 15, 2011.

Mathy Stanislaus,

Assistant Administrator, Office of Solid Waste & Emergency Response.

40 CFR part 262 is amended as follows:

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

■ 1. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922–6925, 6937, and 6938.

■ 2. Section 262.21 is amended by revising paragraph (f)(4) to read as follows:

§ 262.21 Manifest tracking numbers, manifest printing, and obtaining manifests.

* * * * *

(f) ** *

(4) The manifest and continuation sheet must be printed in black ink that can be legibly photocopied, scanned, or faxed, except that the marginal words indicating copy distribution must be printed with a distinct ink color or with another method (*e.g.,* white text against black background in text box, or, black text against grey background in text box) that clearly distinguishes the copy distribution notations from the other text and data entries on the form.

* * * * *

[FR Doc. 2011–15644 Filed 6–21–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906–AA74

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Final rule.

SUMMARY: On September 13, 2010, the Secretary of Health and Human Services (the Secretary) published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) proposing changes to the regulations governing the National Vaccine Injury Compensation Program (VICP). Specifically, the Secretary proposed revisions to the Vaccine Injury Table (Table) to create distinct listings for hepatitis A, trivalent influenza, meningococcal, and human papillomavirus vaccines. The Secretary is now making this amendment to the Table by final rule; it is technical in nature. The four categories of vaccines described in this final rule are already covered vaccines under the VICP (starting in 2004) and are currently listed in a placeholder category (box XIII) in the Table. This final rule will list these vaccines as separate categories on the Table, with no associated injuries noted at this time, in order to help the public identify clearly that these vaccines are covered by the VICP. The changes implemented here are authorized by section 2114(e) of the Public Health Service Act (the Act).

DATES: This regulation is effective July 22, 2011.

FOR FURTHER INFORMATION CONTACT: Geoffrey Evans, M.D., Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration, Room 11C–26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone at (301) 443–6593.

SUPPLEMENTARY INFORMATION: On September 13, 2010, the Secretary published in the **Federal Register** (75 FR 55503, September 13, 2010) an NPRM to revise and amend the Table by moving these vaccines to separate and distinct listings of the Table. The NPRM was issued pursuant to Section 2114(e) of the Act, which directs the Secretary to add to the Table, by rulemaking, coverage of additional vaccines which are recommended by the Centers for Disease Control and Prevention for routine administration to children.

The Department held a 6-month comment period, which ended on March 14, 2011, in connection with this NPRM. The Secretary received one non-substantive comment that was not responsive to the NPRM. A public hearing was held on March 4, 2011, as announced in the **Federal Register** (76 FR 8965, February 16, 2011), but no individual or organization appeared to testify.

Because the Secretary has not received any substantive comments, either written or oral, from any interested individual or organization on the proposals made in the NPRM, and because the Secretary continues to believe the advisability of effectuating such proposals, this final rule implements the proposals made in the NPRM. The rationale for all revisions were explained fully in the Preamble to the NPRM. For the reasons set forth in the NPRM, the Secretary amends the Table in this final rule.

Economic and Regulatory Impact

Executive Order 12866, as amended by Executive Orders 13258 and 13422, directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety, distributive and equity effects). In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule. Executive Order 12866, as amended by Executive Orders 13258 and 13422, requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations which are ''significant'' because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues, require special analysis.

The Secretary has determined that no resources are required to implement the requirements in this final rule. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Fairness Act of 1996, which amended the RFA, the Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities.

The Secretary has also determined that this final rule does not meet the criteria for a major rule as defined by Executive Order 12866, as amended by Executive Orders 13258 and 13422, and would have no major effect on the economy or Federal expenditures. The Secretary has determined that this final rule is not a ''major rule'' within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801.

Similarly, it will not have effects on State, local, and Tribal governments and on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

The Secretary has reviewed this final rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' This final rule would not ''have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This final rule would not adversely affect the following family elements: Family safety, family stability, marital commitment; parental rights in the education, nurture and supervision of their children; family functioning, disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999.

Impact of the New Rule

This final rule is technical in nature. Because the vaccines being added to the Table as separate categories are already included on the Table under Category XIII, this Table will have no effect on current or potential petitioners other than to help clarify which vaccines are covered by the VICP. This final rule would not prevent otherwise eligible individuals with claims of injuries or deaths allegedly resulting from the hepatitis A, trivalent influenza, meningococcal and human papillomavirus vaccines from filing claims with the VICP and would not otherwise affect such petitioners.

Paperwork Reduction Act

This final rule does not have any information collection requirements.

Dated: May 2, 2011.

Mary Wakefield,

Administrator, Health Resources and Services Administration.

Approved: June 16, 2011.

Kathleen Sebelius,

Secretary.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, and Immunization.

Accordingly, 42 CFR part 100 is amended as set forth below:

PART 100—VACCINE INJURY COMPENSATION

■ 1. The authority citation for 42 CFR part 100 continues to read as follows:

Authority: Secs. 312 and 313 of Pub. L. 99–660, 100 Stat. 3779–3782 (42 U.S.C. 300aa–1 note); sec. 2114(c) and (e) of the PHS Act (42 U.S.C. 300aa–14(c) and (e)); sec. 2115(a)(3)(B) of the PHS Act (42 U.S.C. 300aa–15(a)(3)(B)); sec. 904(b) of Pub. L. 105–34, 111 Stat. 873; sec. 1503 of Pub. L. 105–277, 112 Stat. 2681–741; and sec. 523(a) of Pub. L. 106–170, 113 Stat. 1927–1928.

■ 2. Amend § 100.3 by revising the Vaccine Injury Table following paragraph (a), revising paragraph (c)(1), redesignating paragraph (c)(5) as paragraph (c)(8) and revising newly designated paragraph (c)(8), and adding new paragraphs (c)(5), (c)(6), and (c)(7), to read as follows:

§ 100.3 Vaccine injury table

(a) * * *

VACCINE INJURY TABLE

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT).	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Brachial Neuritis	2–28 days.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP–Hib).	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Encephalopathy (or encephalitis)	72 hours.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
III. Measles, mumps, and rubella vaccine or any of its components (e.g., MMR, MR, M, R).	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Encephalopathy (or encephalitis)	5–15 days (not less than 5 days and not more than 15 days).
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
IV. Vaccines containing rubella virus (e.g., MMR, MR, R).	A. Chronic arthritis	7–42 days.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
V. Vaccines containing measles virus (e.g., MMR, MR, M).	A. Thrombocytopenic purpura	7–30 days.
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient.	6 months.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
VI. Vaccines containing polio live virus (OPV).	A. Paralytic Polio	
	—in a non-immunodeficient recipient	30 days.
	—in an immunodeficient recipient	6 months.
	—in a vaccine associated community case	Not applicable.
	B. Vaccine-Strain Polio Viral Infection.	
	—in a non-immunodeficient recipient	30 days.
	—in an immunodeficient recipient	6 months.
	—in a vaccine associated community case	Not applicable.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.

VACCINE INJURY TABLE—Continued

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
VII. Vaccines containing polio inactivated virus (e.g., IPV).	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Any acute complication or sequela (including death of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed..	Not applicable.
VIII. Hepatitis B. vaccines	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
IX. Hemophilus influenzae type b polysaccharide conjugate vaccines.	No Condition Specified	Not applicable.
X. Varicella vaccine	No Condition Specified	Not applicable.
XI. Rotavirus vaccine	No Condition Specified	Not applicable.
XII. Pneumococcal conjugate vaccines	No Condition Specified	Not applicable.
XIII. Hepatitis A vaccines	No Condition Specified	Not applicable.
XIV. Trivalent influenza vaccines	No Condition Specified	Not applicable.
XV. Meningococcal vaccines	No Condition Specified	Not applicable.
XVI. Human papillomavirus (HPV) vaccines.	No Condition Specified	Not applicable.
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage.	No Condition Specified	Not applicable.

* * * * *

(c) * * * (1) Except as provided in paragraph (c)(2), (3), (4), (5), (6), or (7) of this section, the revised Table of Injuries set forth in paragraph (a) of this section and the Qualifications and Aids to Interpretation set forth in paragraph (b) of this section apply to petitions for compensation under the Program filed with the United States Court of Federal Claims on or after March 24, 1997. Petitions for compensation filed before such date shall be governed by section 2114(a) and (b) of the Public Health Service Act as in effect on January 1, 1995, or by § 100.3 as in effect on March 10, 1995 (see 60 FR 7678, *et seq.,* February 8, 1995), as applicable.

* * * * *

(5) Hepatitis A vaccines (Item XIII of the Table) are included on the Table as of December 1, 2004.

(6) Trivalent influenza vaccines (Item XIV of the Table) are included on the Table as of July 1, 2005.

(7) Meningococcal vaccines and human papillomavirus vaccines (Items XV and XVI of the Table) are included on the Table as of February 1, 2007.

(8) Other new vaccines (Item XVII of the Table) will be included in the Table as of the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines. An amendment to this section will be published in the **Federal Register** to announce the effective date of such a tax.

* * * * *

[FR Doc. 2011–15617 Filed 6–21–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2011–0002; Internal Agency Docket No. FEMA–8185]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date.

DATES: *Effective Dates:* The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact David Stearrett, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2953.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the NFIP, 42 U.S.C. 4001 *et seq.;* unless an appropriate public body adopts adequate floodplain management

measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, FEMA has identified the Special Flood Hazard Areas (SFHAs) in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year, on FEMA's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region I				
Massachusetts: Auburn, Town of, Worcester County.	250292	March 2, 1973, Emerg; June 1, 1978, Reg; July 4, 2011, Susp.	July 4, 2011	July 4, 2011.
Berlin, Town of, Worcester County	250294	August 11, 1975, Emerg; June 18, 1980, Reg; July 4, 2011, Susp.	* Do.	Do.
Blackstone, Town of, Worcester County	250295	November 2, 1973, Emerg; September 30, 1977, Reg; July 4, 2011, Susp.	Do.	Do.
Bolton, Town of, Worcester County	250296	March 10, 1975, Emerg; June 18, 1980, Reg; July 4, 2011, Susp.	Do.	Do.
Boylston, Town of, Worcester County	250297	August 26, 1975, Emerg; July 2, 1981, Reg; July 4, 2011, Susp.	Do.	Do.
Charlton, Town of, Worcester County	250299	June 10, 1975, Emerg; July 19, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Clinton, Town of, Worcester County	250300	May 26, 1977, Emerg; June 15, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Douglas, Town of, Worcester County	250301	January 29, 1975, Emerg; June 1, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Dudley, Town of, Worcester County	250302	June 23, 1975, Emerg; June 15, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Grafton, Town of, Worcester County	250306	July 29, 1975, Emerg; May 2, 1983, Reg; July 4, 2011, Susp.	Do.	Do.
Harvard, Town of, Worcester County	250308	June 25, 1975, Emerg; June 15, 1983, Reg; July 4, 2011, Susp.	Do.	Do.

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Hopedale, Town of, Worcester County	250310	June 23, 1975, Emerg; July 19, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Lancaster, Town of, Worcester County	250312	March 7, 1975, Emerg; July 5, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Leicester, Town of, Worcester County	250313	July 22, 1975, Emerg; July 5, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Mendon, Town of, Worcester County	250316	January 22, 1976, Emerg; July 19, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Milford, Town of, Worcester County	250317	August 11, 1975, Emerg; July 5, 1984, Reg; July 4, 2011, Susp.	Do.	Do.
Millbury, Town of, Worcester County	250318	May 4, 1973, Emerg; July 2, 1979, Reg; July 4, 2011, Susp.	Do.	Do.
Millville, Town of, Worcester County	250319	March 7, 1975, Emerg; July 19, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Northborough, Town of, Worcester County	250321	June 10, 1975, Emerg; November 15, 1979, Reg; July 4, 2011, Susp.	Do.	Do.
Northbridge, Town of, Worcester County	250322	January 24, 1975, Emerg; June 15, 1983, Reg; July 4, 2011, Susp.	Do.	Do.
Oxford, Town of, Worcester County	250325	July 24, 1975, Emerg; January 20, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Paxton, Town of, Worcester County	250326	October 29, 1980, Emerg; February 18, 1981, Reg; July 4, 2011, Susp.	Do.	Do.
Shrewsbury, Town of, Worcester County	250332	April 11, 1975, Emerg; June 4, 1980, Reg; July 4, 2011, Susp.	Do.	Do.
Southborough, Town of, Worcester County	250333	August 11, 1975, Emerg; October 15, 1981, Reg; July 4, 2011, Susp.	Do.	Do.
Southbridge, Town of, Worcester County	250334	May 14, 1974, Emerg; March 15, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Spencer, Town of, Worcester County	250335	November 5, 1975, Emerg; July 2, 1981, Reg; July 4, 2011, Susp.	Do.	Do.
Sturbridge, Town of, Worcester County	250337	July 22, 1975, Emerg; July 19, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Sutton, Town of, Worcester County	250338	May 29, 1975, Emerg; June 1, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Upton, Town of, Worcester County	250340	September 2, 1975, Emerg; August 2, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Uxbridge, Town of, Worcester County	250341	May 5, 1975, Emerg; June 1, 1983, Reg; July 4, 2011, Susp.	Do.	Do.
Webster, Town of, Worcester County	250343	July 28, 1975, Emerg; July 5, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
West Boylston, Town of, Worcester County	250345	November 24, 1975, Emerg; July 2, 1981, Reg; July 4, 2011, Susp.	Do.	Do.
Westborough, Town of, Worcester County	250344	July 22, 1975, Emerg; May 15, 1980, Reg; July 4, 2011, Susp.	Do.	Do.
Worcester, City of, Worcester County	250349	January 15, 1974, Emerg; August 15, 1980, Reg; July 4, 2011, Susp.	Do.	Do.
Region III				
Pennsylvania: Driftwood, Borough of, Cameron County.	420245	April 15, 1974, Emerg; July 16, 1979, Reg; July 4, 2011, Susp.	Do.	Do.
Emporium, Borough of, Cameron County	420246	May 15, 1974, Emerg; February 1, 1978, Reg; July 4, 2011, Susp.	Do.	Do.
Gibson, Township of, Cameron County	421130	March 8, 1974, Emerg; September 1, 1977, Reg; July 4, 2011, Susp.	Do.	Do.
Grove, Township of, Cameron County	421128	March 4, 1974, Emerg; July 18, 1977, Reg; July 4, 2011, Susp.	Do.	Do.
Lumber, Township of, Cameron County	421129	March 6, 1974, Emerg; January 5, 1978, Reg; July 4, 2011, Susp.	Do.	Do.
Portage, Township of, Cameron County	421132	March 8, 1974, Emerg; August 15, 1978, Reg; July 4, 2011, Susp.	Do.	Do.
Shippen, Township of, Cameron County	421103	March 11, 1974, Emerg; April 17, 1978, Reg; July 4, 2011, Susp.	Do.	Do.
West Virginia: Nicholas County, Unincorporated Areas.	540146	June 30, 1976, Emerg; April 5, 1994, Reg; July 4, 2011, Susp.	Do.	Do.
Richmond, City of, Nicholas County	540147	November 29, 1974, Emerg; September 27, 1991, Reg; July 4, 2011, Susp.	Do.	Do.
Summersville, City of, Nicholas County	540148	February 18, 1975, Emerg; August 24, 1984, Reg; July 4, 2011, Susp.	Do.	Do.
Region IV				
Florida: Caryville, Town of, Washington County.	120321	July 9, 1975, Emerg; February 4, 1988, Reg; July 4, 2011, Susp.	Do.	Do.

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Chipley, City of, Washington County	120325	January 16, 1975, Emerg; January 1, 1987, Reg; July 4, 2011, Susp.	Do.	Do.
Ebro, Town of, Washington County	120629	N/A, Emerg; March 19, 1996, Reg; July 4, 2011, Susp.	Do.	Do.
Vernon, City of, Washington County	120322	September 26, 1975, Emerg; January 1, 1987, Reg; July 4, 2011, Susp.	Do.	Do.
Washington County, Unincorporated Areas	120407	September 29, 1975, Emerg; June 17, 1991, Reg; July 4, 2011, Susp.	Do.	Do.
Wausau, Town of, Washington County	120632	N/A, Emerg; March 30, 1998, Reg; July 4, 2011, Susp.	Do.	Do.
Kentucky: Allen County, Unincorporated Areas.	210267	February 10, 1994, Emerg; March 1, 1995, Reg; July 4, 2011, Susp.	Do.	Do.
Boyle County, Unincorporated Areas	210322	July 20, 1976, Emerg; May 15, 1986, Reg; July 4, 2011, Susp.	Do.	Do.
Danville, City of, Boyle County	210019	August 8, 1975, Emerg; September 27, 1985, Reg; July 4, 2011, Susp.	Do.	Do.
Junction City, City of, Boyle County	210377	October 16, 1997, Emerg; September 30, 1998, Reg; July 4, 2011, Susp.	Do.	Do.
Perryville, City of, Boyle County	210020	July 21, 1975, Emerg; December 3, 1987, Reg; July 4, 2011, Susp.	Do.	Do.
Scottsville, City of, Allen County	210001	June 11, 1975, Emerg; September 27, 1985, Reg; July 4, 2011, Susp.	Do.	Do.
Mississippi: Bay Springs, Town of, Jasper County.	280087	July 3, 1980, Emerg; June 17, 1986, Reg; July 4, 2011, Susp.	Do.	Do.
Byhalia, Town of, Marshall County	280112	April 29, 1975, Emerg; June 18, 1987, Reg; July 4, 2011, Susp.	Do.	Do.
Heidelberg, Town of, Jasper County	280088	January 30, 1975, Emerg; January 1, 1987, Reg; July 4, 2011, Susp.	Do.	Do.
Holly Springs, City of, Marshall County	280113	March 11, 1975, Emerg; August 5, 1985, Reg; July 4, 2011, Susp.	Do.	Do.
Jasper County, Unincorporated Areas	280302	August 12, 2003, Emerg; December 1, 2003, Reg; July 4, 2011, Susp.	Do.	Do.
Marshall County, Unincorporated Areas	280274	August 4, 1986, Emerg; January 17, 1991, Reg; July 4, 2011, Susp.	Do.	Do.
Potts Camp, Town of, Marshall County	280114	March 31, 1975, Emerg; August 5, 1985, Reg; July 4, 2011, Susp.	Do.	Do.
Region V				
Indiana: Albany, Town of, Delaware County	180314	June 13, 1975, Emerg; June 15, 1979, Reg; July 4, 2011, Susp.	Do.	Do.
Delaware County, Unincorporated Areas	180051	June 13, 1975, Emerg; March 16, 1981, Reg; July 4, 2011, Susp.	Do.	Do.
Eaton, Town of, Delaware County	180052	November 11, 1975, Emerg; June 15, 1979, Reg; July 4, 2011, Susp.	Do.	Do.
Muncie, City of, Delaware County	180053	April 4, 1975, Emerg; January 16, 1981, Reg; July 4, 2011, Susp.	Do.	Do.
Yorktown, Town of, Delaware County	180361	March 18, 1976, Emerg; March 16, 1981, Reg; July 4, 2011, Susp.	Do.	Do.
Region VI				
Arkansas: Conway County, Unincorporated Areas.	050426	January 7, 1983, Emerg; June 3, 1986, Reg; July 4, 2011, Susp.	Do.	Do.
Morrilton, City of, Conway County	050044	June 6, 1975, Emerg; March 15, 1982, Reg; July 4, 2011, Susp.	Do.	Do.
Plumerville, City of, Conway County	050364	September 15, 1983, Emerg; January 17, 1986, Reg; July 4, 2011, Susp.	Do.	Do.
Louisiana: Union Parish, Unincorporated Areas.	220359	May 1, 1979, Emerg; March 1, 1987, Reg; July 4, 2011, Susp.	Do.	Do.
Oklahoma: Goodwell, Town of, Texas County.	400383	June 6, 1980, Emerg; January 18, 1988, Reg; July 4, 2011, Susp.	Do.	Do.
Guymon, City of, Texas County	400243	February 5, 1981, Emerg; June 19, 1985, Reg; July 4, 2011, Susp.	Do.	Do.
Region VII				
Missouri: Holden, City of, Johnson County	290714	October 14, 1996, Emerg; March 1, 2001, Reg; July 4, 2011, Susp.	Do.	Do.
Knob Noster, City of, Johnson County	290724	August 7, 1995, Emerg; November 7, 2001, Reg; July 4, 2011, Susp.	Do.	Do.
Saint Mary, City of, Sainte Genevieve County.	290326	November 9, 1973, Emerg; September 15, 1977, Reg; July 4, 2011, Susp.	Do.	Do.
Sainte Genevieve, City of, Sainte Genevieve County.	290325	December 19, 1973, Emerg; September 30, 1977, Reg; July 4, 2011, Susp.	Do.	Do.

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
West Plains, City of, Howell County	290166	December 19, 1973, Emerg; May 19, 1981, Reg; July 4, 2011, Susp.	Do.	Do.
Willow Springs, City of, Howell County	290167	July 2, 1974, Emerg; August 15, 1979, Reg; July 4, 2011, Susp.	Do.	Do.

* Do. = Ditto.
Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Dated: June 7, 2011.

Sandra K. Knight,

Deputy Federal Insurance and Mitigation Administrator, Mitigation.

[FR Doc. 2011–15520 Filed 6–21–11; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA–2011–0002]

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: Base (1% annual-chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated in the table below.

ADDRESSES: The final BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–4064, or (e-mail) *luis.rodriguez1@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Federal Insurance and Mitigation Administrator has resolved any appeals resulting from this notification.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community. The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This final rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This final rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This final rule meets the applicable standards of Executive Order 12988.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is amended as follows:

PART 67—[AMENDED]

■ 1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

■ 2. The tables published under the authority of § 67.11 are amended as follows:

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected
Elmore County, Alabama, and Incorporated Areas Docket No.: FEMA–B–1114			
Tallapoosa River	Approximately 3.0 miles downstream of Thurlow Dam Approximately 1.7 miles downstream of Thurlow Dam	+210 +214	City of Tallassee.

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Tallassee
Maps are available for inspection at 3 Freeman Avenue, Tallassee, AL 36078.

New London County, Connecticut (All Jurisdictions) Docket Nos.: FEMA–B–1072 and FEMA–B–1139			
Eightmile River	Approximately 100 feet upstream of Hamburg Road Approximately 700 feet upstream of Hamburg Road	+56 +57	Town of Lyme.
Four Mile River	Approximately 200 feet downstream of the breached dam Approximately 1,200 feet upstream of I–95	+10 +52	Town of Old Lyme.
Four Mile River	Just upstream of the railroad Approximately 1,200 feet downstream of the breached dam.	+10 +10	Town of Old Lyme.
Little River	At the confluence with the Shetucket River Approximately 2,400 feet upstream of Inland Road	+64 +83	Town of Lisbon.
Long Island Sound	Approximately 1,200 feet west of the intersection of Atlantic Avenue and Bridge Street.	+12	Groton Long Point Association.
Long Island Sound	Approximately 3,100 feet south of the intersection of Dimmock Road and Great Neck Road.	+14	Borough of Stonington, City of Groton, City of New London, Noank Fire District, Town of East Lyme, Town of Groton, Town of Old Lyme, Town of Stonington, Town of Waterford.
	Approximately 375 feet southwest of the intersection of Lindberg Road and Oak Street.	+15	
Shunock River	Just upstream of Pendleton Hill Road Approximately 400 feet upstream of Pendleton Hill Road	+29 +30	Town of Stonington.
Susquetonscut Brook	At the confluence with the Yantic River	+119	City of Norwich, Town of Bozrah
	Approximately 800 feet downstream of Lebanon Road	+119	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

Borough of Stonington
Maps are available for inspection at the Borough Hall, 26 Church Street, Stonington, CT 06378.

City of Groton
Maps are available for inspection at the City Municipal Building, 295 Meridian Street, Groton, CT 06340.

City of New London
Maps are available for inspection at City Hall, 181 State Street, New London, CT 06320.

City of Norwich
Maps are available for inspection at City Hall, 100 Broadway, Norwich, CT 06360.

Groton Long Point Association
Maps are available for inspection at the Town Hall, 44 Beach Road, Groton Long Point, CT 06340.

Noank Fire District
Maps are available for inspection at 45 Fort Hill Road, Groton, CT 06340.

Town of Bozrah
Maps are available for inspection at the Town Hall, 1 River Road, Bozrah, CT 06334.

Town of East Lyme

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected

Maps are available for inspection at the East Lyme Town Hall, 108 Pennsylvania Avenue, Niantic, CT 06357.

Town of Groton

Maps are available for inspection at the Town Hall, 175 Shennecossett Parkway, Groton, CT 06340.

Town of Lisbon

Maps are available for inspection at the Town Hall, One Newent Road, Lisbon, CT 06351.

Town of Lyme

Maps are available for inspection at the Lyme Town Hall, 480 Hamburg Road, Old Lyme, CT 06371.

Town of Old Lyme

Maps are available for inspection at the Old Lyme Memorial Town Hall, 52 Lyme Street, Old Lyme, CT 06371.

Town of Stonington

Maps are available for inspection at the Town Hall, 152 Elm Street, Stonington, CT 06378.

Town of Waterford

Maps are available for inspection at the Town Hall, 15 Rope Ferry Road, Waterford, CT 06385.

St. Johns County, Florida, and Incorporated Areas
Docket No.: FEMA–B–1089

Kendall Creek	Approximately 300 feet upstream of Roberts Road	*25	Unincorporated Areas of St. Johns County.
	Approximately 700 feet upstream of Roberts Road	*26	
Orange Grove Branch	Approximately 4,600 feet upstream of Orange Branch Trail.	*26	Unincorporated Areas of St. Johns County.
	Approximately 5,700 feet upstream of Orange Branch Trail.	*27	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

Unincorporated Areas of St. Johns County

Maps are available for inspection at 4020 Lewis Speedway, St. Augustine, FL 32084.

Coles County, Illinois, and Incorporated Areas
Docket No.: FEMA–B–1101

Cassell Creek	Approximately 1,650 feet upstream of the confluence with Town Branch Creek.	+613	City of Charleston.
	Approximately at the upstream side of the railroad (removed).	+619	
Town Branch Creek	Approximately 0.19 mile downstream of the railroad	+616	City of Charleston.
	Approximately 0.08 mile downstream of the railroad	+617	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Charleston

Maps are available for inspection at City Hall, 520 Jackson Avenue, Charleston, IL 61920.

La Salle County, Illinois, and Incorporated Areas
Docket No.: FEMA–B–1104

Bailey Creek	Approximately 0.52 mile downstream of Pontiac Street	+638	Unincorporated Areas of La Salle County, Village of Tonica.
	Approximately 100 feet downstream of I–39	+651	
Bailey Creek Unnamed Tributary.	At the confluence with Bailey Creek	+646	Village of Tonica.
	Approximately 225 feet upstream of IL–251	+652	
Clark Run	At the confluence with the Illinois River	+467	Unincorporated Areas of La Salle County, Village of North Utica.

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected
	Approximately 525 feet downstream of the Illinois and Michigan Canal.	+467	
Fox River	At the confluence with the Illinois River	+474	City of Ottawa, Unincorporated Areas of La Salle County.
	Approximately 0.87 mile upstream of U.S. Route 6/Norris Drive.	+474	
Goose Creek	At the confluence with the Fox River	+474	City of Ottawa, Unincorporated Areas of La Salle County.
	Approximately 100 feet upstream of Champlain Street	+474	
Illinois River	Approximately 0.51 mile downstream of the confluence with Cedar Creek.	+463	City of La Salle, City of Marseilles, City of Oglesby, City of Ottawa, City of Peru, Unincorporated Areas of La Salle County, Village of Naplate, Village of North Utica, Village of Seneca.
	Approximately 1.1 miles upstream of IL–170	+498	
Mendota Creek	Approximately 0.4 mile downstream of 1st Street	+724	City of Mendota, Unincorporated Areas of La Salle County.
	Approximately 0.55 mile upstream of Lakewood Plaza Drive.	+767	
Rat Run	At the confluence with the Illinois River	+495	Unincorporated Areas of La Salle County, Village of Seneca.
	Approximately 125 feet downstream of IL–170	+495	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of La Salle
Maps are available for inspection at City Hall, 745 2nd Street, La Salle, IL 61301.

City of Marseilles
Maps are available for inspection at City Hall, 209 Lincoln Street, Marseilles, IL 61341.

City of Mendota
Maps are available for inspection at City Hall, 800 Washington Street, Mendota, IL 61342.

City of Oglesby
Maps are available for inspection at City Hall, 110 East Walnut Street, Oglesby, IL 61348.

City of Ottawa
Maps are available for inspection at City Hall, 301 West Madison Street, Ottawa, IL 61350.

City of Peru
Maps are available for inspection at City Hall, 1727 4th Street, Peru, IL 61354.

Unincorporated Areas of La Salle County
Maps are available for inspection at the La Salle County Courthouse, Etna Road Complex, 707 East Etna Road, Ottawa, IL 61350.

Village of Naplate
Maps are available for inspection at the Village Hall, 2000 West Ottawa Avenue, Naplate, IL 61350.

Village of North Utica
Maps are available for inspection at the Village Hall, 801 South Clark Street, North Utica, IL 61373.

Village of Seneca
Maps are available for inspection at the Village Hall, 340 North Cash Street, Seneca, IL 61360.

Village of Tonica
Maps are available for inspection at the Village Hall, 308 Uncas Street, Tonica, IL 61370.

Lawrence County, Illinois, and Incorporated Areas
Docket No.: FEMA–B–1125

Brushy Creek	Approximately 100 feet downstream of North 1550th Street (County Route 5).	+437	Unincorporated Areas of Lawrence County.

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected
	At the downstream side of North 1550th Street (County Route 5).	+437	
Wabash River	Approximately 3.5 miles downstream of Wabash Cannonball Railroad Bridge.	+415	City of St. Francisville.
	Approximately 0.5 mile downstream of Wabash Cannonball Railroad Bridge.	+417	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of St. Francisville

Maps are available for inspection at City Hall, 207 South 6th Street, St. Francisville, IL 62460.

Unincorporated Areas of Lawrence County

Maps are available for inspection at the Lawrence County Courthouse, 1100 State Street, Lawrenceville, IL 62439.

Moultrie County, Illinois, and Incorporated Areas
Docket No.: FEMA–B–1101

Dalton City Drain	At the confluence with Marrowbone Creek	+672	Unincorporated Areas of Moultrie County.
	At State Route 128	+687	
Lowe No. 2	Approximately 1,100 feet downstream of Vine Street	+656	Unincorporated Areas of Moultrie County.
	Approximately 540 feet upstream of Progress Street	+662	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

Unincorporated Areas of Moultrie County

Maps are available for inspection at the Moultrie County Courthouse, Planning and Zoning Department, 10 South Main Street, Suite 1, Sullivan, IL 61951.

Black Hawk County, Iowa, and Incorporated Areas
Docket No.: FEMA–B–1060

Big Woods Creek	Approximately 88 feet upstream of Lone Tree Road	+864	City of Cedar Falls, Unincorporated Areas of Black Hawk County.
	Just downstream of Cedar-Wapsi Road	+920	
Big Woods Creek Upper Diversion.	Approximately 0.5 mile upstream of Mount Vernon Road	+870	Unincorporated Areas of Black Hawk County.
	Approximately 0.6 mile upstream of Cedar-Wapsi Road	+875	
Black Hawk Creek	Just upstream of West Shaulis Road	+870	City of Hudson, City of Waterloo,
Unincorporated Areas of Black Hawk County.			
	Approximately 975 feet downstream of Zaneta Road	+891	
Cedar River	Just upstream of Lone Tree Road and I–218	+864	City of Cedar Falls.
	East of Big Woods Road and approximately 0.3 mile south of Dunkerton Road along Illinois Central Gulf Railroad.	+864	
Cedar River	Approximately 0.6 mile downstream of I–218	+859	City of Cedar Falls, City of Waterloo, Unincorporated Areas of Black Hawk County.
	Approximately 2.1 miles upstream of Center Street	+869	
Cedar River Diversion Channel	Approximately 440 feet downstream of State Highway 57	+860	City of Cedar Falls.
	Approximately 1.3 miles upstream of Illinois Central Railroad.	+865	
City View Branch	Approximately 0.3 mile downstream of Independence Avenue.	+847	City of Waterloo.
	Just downstream of Chicago and North Western Railroad	+859	

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected
Crane Creek	Approximately 117 feet downstream of Wheeler Road	+936	City of Dunkerton, Unincorporated Areas of Black Hawk County.
	Just downstream of East Cedar Wapsi Road	+967	
Crossroads Creek	Approximately 91 feet downstream of Hess Road	+845	City of Waterloo.
	Approximately 514 feet upstream of Alexander Drive	+871	
Crossroads Creek Diversion	Approximately 91 feet downstream of Hess Road	+849	City of Waterloo.
	Approximately 0.3 mile upstream of Sarah Drive	+867	
Dry Run Creek Diversion	Approximately 25 feet upstream of 20th Street	+864	City of Cedar Falls.
	Approximately 225 feet downstream of Seerley Boulevard	+866	
Dry Run Creek at Cedar Falls	Approximately 293 feet downstream of Illinois Central Gulf Railroad.	+852	City of Cedar Falls.
	Approximately 540 feet downstream of U.S. Route 20	+928	
Dry Run Creek at Waterloo	Approximately 664 feet downstream of Commercial Street	#2	City of Waterloo.
	Approximately 106 feet upstream of Byron Avenue	+861	
	Approximately 0.5 mile upstream of Kimball Avenue	+942	
Maywood Branch	Approximately 0.4 mile downstream of Bishop Avenue	+855	City of Waterloo.
	Just upstream of Bishop Avenue	+857	
Myers Lake	West end of lake	+838	City of Evansdale.
	East end of lake	+838	
Ponded Area No. 2, from Elk Run Creek, landside of levee.	North end of ponding area, approximately 0.3 mile downstream of LaFayette Road.	+836	City of Evansdale.
	South end of ponding area, approximately 0.4 mile upstream of Gilbert Road.	+836	
Ponded Area No.1 from Elk Run Creek, landside of levee.	North end of ponding area, approximately 150 feet downstream of Gilbert Drive.	+836	City of Evansdale.
	South end of ponding area, approximately 350 feet upstream of State Route 380.	+836	
South West Branch of Dry Run Creek.	Approximately 279 feet downstream of Main Street	+865	City of Cedar Falls.
	Approximately 1.8 miles upstream of Future Greenhill Road.	+921	
Stream No. 13	Approximately 1.0 mile downstream of Wagner Road	+856	City of Waterloo.
	Approximately 364 feet upstream of Airline Highway	+863	
Stream No. 36	Approximately 1.0 mile downstream of Wagner Road	+863	City of Waterloo, Unincorporated Areas of Black Hawk County.
	Approximately 0.4 mile downstream of Dunkerton Road	+870	
Sunnyside Creek	Approximately 0.3 mile downstream of Martin Road	+855	City of Waterloo.
	Approximately 130 feet upstream of 4th Street	+878	
Sunnyside Creek Bypass	Approximately 0.6 mile downstream of Marine Avenue	+861	City of Waterloo.
	Approximately 450 feet upstream of Marine Avenue	+869	
Unnamed Tributary to Big Woods Creek.	Just downstream of Dunkerton Road	+864	City of Cedar Falls.
	Approximately 408 feet west of I–218	+864	
Unnamed Tributary to Big Woods Creek.	Approximately 0.5 mile upstream of Mount Vernon Road	+871	Unincorporated Areas of Black Hawk County.
	Just upstream of Dunkerton Road	+871	
Unnamed Tributary to Cedar River.	Approximately 182 feet downstream of Dunkerton Road	+864	City of Cedar Falls.
	Just upstream of Lone Tree Road	+864	
Wolf Creek	Approximately 0.6 mile downstream of Bike Path	+815	City of La Porte City.
	Approximately 1.3 miles upstream of Main Street	+824	
Wolf Creek Overflow	Approximately 0.4 mile downstream of 8th Street	+815	City of La Porte City, Unincorporated Areas of Black Hawk County.
	Approximately 1.3 miles upstream of Poplar Street	+823	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Cedar Falls

Maps are available for inspection at 220 Clay Street, Cedar Falls, IA 50613.

City of Dunkerton

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected

Maps are available for inspection at 200 Tower Street, Dunkerton, IA 50626.

City of Evansdale

Maps are available for inspection at 123 North Evans Road, Evansdale, IA 50707

City of Hudson

Maps are available for inspection at 525 Jefferson Street, Hudson, IA 50643.

City of La Porte City

Maps are available for inspection at 202 Main Street, La Porte City, IA 50651.

City of Waterloo

Maps are available for inspection at 715 Mulberry Street, Waterloo, IA 50703.

Unincorporated Areas of Black Hawk County

Maps are available for inspection at 316 East 5th Street, Suite 203, Waterloo, IA 50703.

Clinton County, Iowa, and Incorporated Areas
Docket No.: FEMA–B–1100

Mississippi River	Approximately 11.2 miles downstream of U.S. Route 30 ...	+585	City of Camanche, City of Clinton,
Unincorporated Areas of Clinton County.	Approximately 12.8 miles upstream of State Highway 136	+594	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Camanche

Maps are available for inspection at 917 3rd Street, Camanche, IA 52730.

City of Clinton

Maps are available for inspection at 110 5th Avenue South, Clinton, IA 52732.

Unincorporated Areas of Clinton County

Maps are available for inspection at 329 East 11th Street, DeWitt, IA 52742.

Louisa County, Iowa, and Incorporated Areas
Docket No.: FEMA–B–1093

Mississippi River	Approximately 8.3 miles downstream of the confluence with the Iowa River.	+544	Unincorporated Areas of Louisa County.
	Approximately 1.4 miles upstream of the confluence with Michaels Creek.	+552	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

Unincorporated Areas of Louisa County

Maps are available for inspection at the Louisa County Courthouse, 117 South Main Street, Wapello, IA 52653.

Muscatine County, Iowa, and Incorporated Areas
Docket No.: FEMA–B–1089

Mississippi River	Approximately 7.1 miles downstream of State Route 92 ...	+554	City of Muscatine,
Unincorporated Areas of Muscatine County.	Approximately 3.3 miles upstream of the confluence with Pine Creek.	+560	
Mud Creek	Approximately 1.2 miles upstream of Story Avenue	+658	City of Wilton.
	Approximately 1.4 miles upstream of Story Avenue	+658	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected

ADDRESSES

City of Muscatine

Maps are available for inspection at 215 Sycamore Street, Muscatine, IA 52761.

City of Wilton

Maps are available for inspection at 104 East 4th Street, Wilton, IA 52778.

Unincorporated Areas of Muscatine County

Maps are available for inspection at 3610 Park Avenue West, Muscatine, IA 52761.

Hart County, Kentucky, and Incorporated Areas
Docket No.: FEMA–B–1089

Bacon Creek (backwater effects from Nolin Lake).	From the confluence with Nolin Lake to approximately 0.7 mile upstream of Charles Jaggers Road.	+560	Unincorporated Areas of Hart County.
Bacon Creek Tributary 41 (backwater effects from Nolin Lake).	From the confluence with Bacon Creek to approximately 0.5 mile upstream of the confluence with Bacon Creek.	+560	Unincorporated Areas of Hart County.
Cane Run (backwater effects from Nolin Lake).	From the confluence with Nolin Lake to approximately 0.5 mile upstream of the confluence with Cane Run Tributary 11.	+560	Unincorporated Areas of Hart County.
Cane Run Tributary 13 (backwater effects from Nolin Lake).	From the confluence with Nolin Lake to approximately 0.8 mile upstream of the confluence with Nolin Lake.	+560	Unincorporated Areas of Hart County.
Little Dog Creek (backwater effects from Nolin Lake).	From the confluence with Nolin Lake to approximately 1.3 miles upstream of the confluence with Nolin Lake.	+560	Unincorporated Areas of Hart County.
Nolin Lake	Entire shoreline	+560	Unincorporated Areas of Hart County.
Nolin River (backwater effects from Nolin Lake).	From the confluence with Nolin Lake to approximately 3.1 miles downstream of Wheelers Mill Road.	+560	Unincorporated Areas of Hart County.
Nolin River Tributary 2 (backwater effects from Nolin Lake).	From the confluence with Nolin Lake to approximately 1,692 feet upstream of the confluence with Nolin Lake.	+560	Unincorporated Areas of Hart County.
Nolin River Tributary 24 (backwater effects from Nolin Lake).	From the confluence with Nolin Lake to approximately 268 feet upstream of Robbin Lane.	+560	Unincorporated Areas of Hart County.

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

Unincorporated Areas of Hart County

Maps are available for inspection at the Hart County Courthouse, 200 Main Street, Munfordville, KY 42765.

Meade County, Kentucky, and Incorporated Areas
Docket No.: FEMA–B–1089

Ohio River	Approximately 2.8 miles upstream of the confluence with Watson Run (River Mile 683.25).	+421	City of Brandenburg, Unincorporated Areas of Meade County.
	Approximately 0.7 mile downstream of Lock and Dam No. 43 (River Mile 634.0).	+442	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Brandenburg

Maps are available for inspection at 737 High Street, Brandenburg, KY 40108.

Unincorporated Areas of Meade County

Maps are available for inspection at the Office of the Executive County Judge, 516 Fairway Drive, Brandenburg, KY 40108.

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected
Marion County, Mississippi, and Incorporated Areas Docket No.: FEMA–B–1117			
Pearl River	Approximately 5.5 miles downstream of State Highway 98	+134	City of Columbia, Unincorporated Areas of Marion County.
	Approximately 5 miles upstream of State Highway 35	+154	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Columbia

Maps are available for inspection at 201 2nd Street, Columbia, MS 39429.

Unincorporated Areas of Marion County

Maps are available for inspection at 250 Broad Street, Columbia, MS 39429.

Prentiss County, Mississippi, and Incorporated Areas Docket No.: FEMA–B–1083			
Tennessee-Tombigbee Waterway (Bay Springs Lake).	Entire shoreline within community	+420	Unincorporated Areas of Prentiss County.

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

Unincorporated Areas of Prentiss County

Maps are available for inspection at the Prentiss County Courthouse, 2301 North 2nd Street, Booneville, MS 38829.

Gasconade County, Missouri, and Incorporated Areas Docket No.: FEMA–B–1115			
Brushy Fork (backwater effects from Missouri River).	From the confluence with First Creek to approximately 0.64 mile upstream of the confluence with Howard Creek.	+526	Unincorporated Areas of Gasconade County.
Cole Creek (backwater effects from Missouri River).	From the confluence with the Missouri River to approximately 1.4 miles upstream of the confluence with the Missouri River.	+522	Unincorporated Areas of Gasconade County.
First Creek (backwater effects from Missouri River).	From the confluence with the Gasconade River to approximately 1,320 feet upstream of the confluence with First Creek Tributary 6.	+526	Unincorporated Areas of Gasconade County.
First Creek Tributary 6 (backwater effects from Missouri River).	From the confluence with First Creek to approximately 1,478 feet upstream the confluence with First Creek.	+526	Unincorporated Areas of Gasconade County.
Frene Creek (backwater effects from Missouri River).	From the confluence with the Missouri River to approximately 68 feet downstream of 14th Street.	+519	City of Hermann, Unincorporated Areas of Gasconade County.
Frene Creek Tributary 8 (backwater effects from Missouri River).	From the confluence with Frene Creek to approximately 314 feet upstream of Schiefers Branch Road.	+519	City of Hermann, Unincorporated Areas of Gasconade County.
Gasconade River (backwater effects from Missouri River).	From the confluence with the Missouri River to approximately 0.58 mile downstream of the confluence with Gasconade River Tributary 26.	+526	Unincorporated Areas of Gasconade County.
Howard Creek (backwater effects from Missouri River).	From the confluence with Brushy Fork to approximately 0.74 mile upstream of the confluence with Brushy Fork.	+526	Unincorporated Areas of Gasconade County.
Little Berger Creek (backwater effects from Missouri River).	From the confluence with the Missouri River to Missouri Route 100.	+515	Unincorporated Areas of Gasconade County.
Missouri River	Approximately 0.7 mile upstream of the confluence with Little Berger Creek in Franklin County.	+516	Unincorporated Areas of Gasconade County.
	Approximately 690 feet downstream of the confluence with Shawnee Creek.	+528	

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected
Richland Creek (backwater effects from Missouri River).	From the confluence with the Gasconade River to approximately 1,816 feet downstream of the confluence with Richland Creek Tributary 2.	+526	Unincorporated Areas of Gasconade County.
Sugar Creek (backwater effects from Missouri River).	From approximately 0.68 mile downstream of Missouri Route J to the confluence with the Gasconade River.	+526	Unincorporated Areas of Gasconade County.

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Hermann
Maps are available for inspection at 1902 Jefferson Street, Hermann, MO 65041.

Unincorporated Areas of Gasconade County
Maps are available for inspection at 119 East 1st Street, Hermann, MO 65041.

McHenry County, North Dakota, and Incorporated Areas
Docket No.: FEMA–B–1126

Mouse River	Approximately 1.25 miles upstream of U.S. Route 2	+1462	Unincorporated Areas of McHenry County.
	Approximately 3.26 miles upstream of U.S. Route 2	+1462	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

Unincorporated Areas of McHenry County
Maps are available for inspection at 407 Main Street South, Towner, ND 58788.

Darke County, Ohio, and Incorporated Areas
Docket No.: FEMA–B–1114

Indian Creek	Approximately 300 feet upstream of the confluence with Swamp Creek.	+968	Village of Versailles.
	Approximately 1,000 feet upstream of the confluence with Swamp Creek.	+968	
Painter Creek	Approximately 50 feet upstream of State Highway 49	+1030	Unincorporated Areas of Darke County.
	Just downstream of Hollansburg-Sampson Road	+1049	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

Unincorporated Areas of Darke County
Maps are available for inspection at 520 South Broadway Street, Greenville, OH 45331.

Village of Versailles
Maps are available for inspection at 177 North Center Street, Versailles, OH 45380.

Seminole County, Oklahoma, and Incorporated Areas
Docket No.: FEMA–B–1064

Tributary 3 of Magnolia Creek	Approximately 1.3 miles upstream of the confluence with Tributary 1 of Tributary 3 of Magnolia Creek.	+953	Unincorporated Areas of Seminole County.
	Approximately 1.7 miles upstream of the confluence with Tributary 1 of Tributary 3 of Magnolia Creek.	+967	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected

ADDRESSES

Unincorporated Areas of Seminole County

Maps are available for inspection at 110 South Wewoka Avenue, Wewoka, OK 74884.

Potter County, Pennsylvania (All Jurisdictions)
Docket No.: FEMA–B–1110

Freeman Run	Approximately 0.7 mile downstream of State Route 607 (Main Street).	+1311	Township of Portage.
	Approximately 0.6 mile downstream of State Route 607 (Main Street).	+1316	
Oswayo Creek	Approximately 1.8 miles upstream of State Route 44	+1567	Township of Clara.
	Approximately 2.2 miles upstream of State Route 44	+1572	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

Township of Clara

Maps are available for inspection at the Clara Township Building, 566 Clara Road, Shinglehouse, PA 16748.

Township of Portage

Maps are available for inspection at the Portage Township Hall, 23 State Street, Austin, PA 16720.

Robertson County, Texas, and Incorporated Areas
Docket No.: FEMA–B–1091

Little Brazos River	At the confluence with Lost Creek	+268	Unincorporated Areas of Robertson County.
	Just downstream of Gifford Hill Road	+276	
Lost Creek	At the confluence with the Little Brazos River	+268	Unincorporated Areas of Robertson County.
	Just downstream of Union Pacific Railroad	+272	
	Approximately 1,900 feet downstream of Black Jack Road	+305	
	Approximately 800 feet upstream of Old Henry Prairie Road.	+338	
Sandy Creek	At the confluence with the Little Brazos River	+274	Unincorporated Areas of Robertson County.
	Just downstream of Vaughn Lane	+287	
	Just upstream of Union Pacific Railroad	+302	
	Approximately 1,970 feet upstream of the confluence with Sandy Creek Tributary 3.	+320	
Sandy Creek Tributary 2	At the confluence with Sandy Creek	+312	Unincorporated Areas of Robertson County.
	Approximately 1,400 feet upstream of the confluence with Sandy Creek.	+314	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

Unincorporated Areas of Robertson County

Maps are available for inspection at 102 East Decherd Street, Franklin, TX 77856.

Chittenden County, Vermont (All Jurisdictions)
Docket Nos.: FEMA–B–1072 and FEMA–B–1139

Browns River	Approximately 1,500 feet upstream of Brown River Road (Route 128).	+354	Town of Essex, Town of Jericho, Town of Underhill, Town of Westford.
	Approximately 100 feet upstream of Stevensville Road	+819	

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected
Winooski River	Approximately 450 feet upstream of Essex Road (Park Street).	+286	Town of Bolton, Town of Essex, Town of Jericho, Town of Williston, Village of Essex Junction.
	Approximately 1,500 feet upstream of Central Vermont Railroad.	+356	
Winooski River	Approximately 0.7 mile upstream of the confluence with Lake Champlain.	+102	City of Burlington, City of South Burlington, City of Winooski, Town of Colchester.
	Approximately 1,200 feet downstream of Main Street/ Colchester Avenue.	+116	
Winooski River	Approximately 1,200 feet downstream of I–89	+165	City of South Burlington, Town of Colchester.
	Approximately 1,100 feet upstream of I–89	+167	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Burlington
Maps are available for inspection at City Hall, 149 Church Street, Burlington, VT 05401.

City of South Burlington
Maps are available for inspection at City Hall, 575 Dorset Street, South Burlington, VT 05403.

City of Winooski
Maps are available for inspection at 27 West Allen Street, Winooski, VT 05404.

Town of Bolton
Maps are available for inspection at the Town Hall, 3045 Theodore Roosevelt Highway, Bolton, VT 05676.

Town of Colchester
Maps are available for inspection at 781 Blakely Road, Colchester, VT 05446.

Town of Essex
Maps are available for inspection at the Essex Town Hall, 81 Main Street, Essex Junction, VT 05452.

Town of Jericho
Maps are available for inspection at the Town Hall, 67 Vermont Route 15, Jericho, VT 05465.

Town of Underhill
Maps are available for inspection at the Underhill Town Hall, 12 Pleasant Valley Road, Underhill Center, VT 05490.

Town of Westford
Maps are available for inspection at the Town Office, 1713 Vermont Route 128, Westford, VT 05494.

Town of Williston
Maps are available for inspection at the Town Hall, 7900 Williston Road, Williston, VT 05495.

Village of Essex Junction
Maps are available for inspection at Lincoln Hall, 2 Lincoln Street, Essex Junction, VT 05452.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: May 17, 2011.

Sandra K. Knight,

Deputy Federal Insurance and Mitigation Administrator, Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2011–15507 Filed 6–21–11; 8:45 am]

BILLING CODE 9110–12–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 11–932; MB Docket No. 09–219; RM–11581]

Radio Broadcasting Services; Brackettville, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division grants a Petition for Rule Making issued at the request of RF Services, Inc., licensee of a new FM station at Rocksprings, Texas, that requests the deletion of vacant Channel 234A at Brackettville to accommodate the hybrid application, which requests the substitution of Channel 234C3 for Channel 235C3 at Rocksprings, Texas, reallotment of Channel 234C3 from Rocksprings, to Brackettville, Texas, and modification of the new FM station authorization. *See* File No. BNPH–20091019AFF.

DATES: Effective July 5, 2011.

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

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

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order,* MB Docket No. 09–219, adopted May 19, 2011, and released May 20, 2011. The *Notice of Proposed Rule Making* proposed the deletion of vacant Channel 234A at Brackettville. *See* 75 FR 4037, published January 26, 2010. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Information Center, 445 12th Street, SW., Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *http://www.BCPIWEB.com.* This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

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

Authority: 47 U.S.C. 154, 303, 334, 336, and 339.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by removing Brackettville, Channel 234A.

[FR Doc. 2011–15610 Filed 6–21–11; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 76, No. 120
Wednesday, June 22, 2011

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 30

[Docket No. PRM–30–65; NRC–2011–0134]

Petition for Rulemaking Submitted by Annette User on Behalf of GE Osmonics, Inc.

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; receipt and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is publishing for comment a notice of receipt of a petition for rulemaking, dated April 18, 2011, which was filed with the NRC by Annette User on behalf of GE Osmonics, Inc (the petitioner). The petition was docketed by the NRC on April 20, 2011, and has been assigned Docket No. PRM–30–65. The petitioner requests that the NRC amend its regulations regarding the commercial distribution of byproduct material to allow recipients of exempt quantities of polymer (polycarbonate or polyester) track etch (PCTE) membranes that have been irradiated with mixed fission products (MFP) to commercially redistribute the material without a license.

DATES: Submit comments by September 6, 2011. 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: Please include Docket ID NRC–2011–0134 in the subject line of your comments. For instructions on submitting comments and accessing documents related to this action, see ''Submitting Comments and Accessing Information'' in the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments by any one of the following methods:

- *Federal rulemaking Web site:* Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2011–0134. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668; e-mail: *Carol.Gallagher@nrc.gov*.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *E-mail comments to: Rulemaking.Comments@nrc.gov.* If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301–415–1966.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852 between 7:30 a.m. and 4:15 p.m. during Federal workdays (Telephone 301–415–1966).
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.

FOR FURTHER INFORMATION CONTACT: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–492–3667, e-mail: *Cindy.Bladey@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site, *http://www.regulations.gov.* 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.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this document using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, or 301–415–4737, or by e-mail to *PDR.Resource@nrc.gov.*
- *Federal Rulemaking Web Site:* Public comments and supporting materials related to this action can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2011–0134.

Background

GE Osmonics, Inc. (GE) is a manufacturer of PCTE/MFP membranes. PCTE membranes are irradiated with MFP in a GE-owned irradiator housed inside a reactor at Texas A&M University. The irradiation is performed by the university, under contract to GE and under Texas A&M NRC License No. R–83, to produce an ion track. After irradiation and a period of storage for decay, the university ships the PCTE/MFP membranes to GE's Bryan, Texas facility, which receives, possesses, and processes the membranes under a Texas Agreement State license. Byproduct material which remains after decay is embedded/tightly bound in the membrane. At the Bryan, Texas facility, GE chemically etches the membranes to produce the desired pore size.

Until February 2010, GE transferred the PCTE/MFP membranes to two GE redistribution facilities in Westborough, Massachusetts, and Minnetonka, Minnesota. However, GE states that as part of the Bryan, Texas license renewal process, the Texas Department of State Health Services advised GE that it could no longer transfer the PCTE/MFP membranes to those two facilities for commercial distribution without a specific exempt distribution license from the NRC. GE states that it has submitted such a license application to the NRC.

Annette User, on behalf of GE, submitted a petition for rulemaking dated April 18, 2011, requesting that the NRC amend its regulations regarding the

commercial distribution of byproduct material to allow recipients of exempt quantities of PCTE/MFP to commercially redistribute the material without a license. The petitioner states that once GE obtains an exempt quantity distribution license from the NRC, there should be no significant health, safety or common defense and security concerns that would preclude its customers from further redistribution of the material without a license.

The NRC has determined that the petition meets the threshold sufficiency requirements for a petition for rulemaking under Title 10 of the Code of Federal Regulations (10 CFR), 2.802, and the petition has been docketed as PRM–30–65. The NRC is requesting public comment on the petition for rulemaking.

Discussion of the Petition

The petitioner states that under current NRC regulations (and with a specific license, if approved), it is able to manufacture and commercially distribute PCTE/MFP membranes to that segment of its customers that will not be further distributing the product for commercial purposes. However, current regulations at 10 CFR 30.18(c) and (d) prohibit the petitioner from distribution of the material to a substantial portion of its customer base that would commercially redistribute the material if authorized to do so.

The petitioner proposes that 10 CFR 30.18 be modified as follows:

(c) This section does not authorize for purposes of commercial distribution the production, packaging, repackaging, or transfer of byproduct material or the incorporation of byproduct material into products intended for commercial distribution, except as provided in § 30.18(f).

(d) Except as provided in § 30.18(f), no person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in § 30.71 Schedule B, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.18 of this chapter, which license states that the byproduct material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of an Agreement State.

(f) Polymer track etch membrane containing mixed fission products in individual quantities, each of which does not exceed the applicable quantity set forth in § 30.71 Schedule B, may be redistributed commercially to any person without the redistributor obtaining a specific license under § 32.18, so long as the person who initially manufactures, processes, produces, packages, repackages, or transfers quantities of byproduct material for commercial distribution obtains a specific license under § 32.18.

The petitioner has separately requested an NRC exempt distribution license under 10 CFR 32.18 to authorize it to commercially distribute the PCTE/MFP membranes to its customers, and believes that once it obtains the license, there should be no significant health, safety or common defense and security concerns that would preclude its customers from further redistribution without a license. The petitioner included an analysis in the petition for rulemaking document to support its belief. The petitioner states that PCTE/MFP membranes are used in a wide variety of research, medical, academic, scientific and industrial applications. In particular, PCTE/MFP membranes are used in pharmaceutical, medical device, and water filtration applications. The petitioner believes that the amendments are necessary to allow it to distribute the PCTE/MFP membranes to the full range of its customers.

Dated at Rockville, Maryland this 16th day of June, 2011.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2011–15593 Filed 6–21–11; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0570; Directorate Identifier 2011–NM–014–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A300 Series Airplanes; Model A310 Series Airplanes; and Model A300 B4–600, B4–600R, and F4–600R Series Airplanes, and Model C4–605R Variant F Airplanes (Collectively Called A300–600 Series 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 products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

* * * * *

A recent analysis conducted by the manufacturer showed a particular risk for explosive failure of the * * * hydraulic accumulator.

This condition, if not detected and corrected, might, for some aeroplane installations, lead to damage to all three hydraulic circuits, possibly resulting in loss of control of the aeroplane or could, for certain other aeroplane installations, lead to an undetected fire in the wheel bay.

* * * * *

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

DATES: We must receive comments on this proposed AD by August 8, 2011.

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

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

For service information identified in this proposed AD, contact Airbus SAS—EAW (Airworthiness Office), 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; *e-mail: account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. 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;* or in person at the Docket Operations office 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 Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116,

Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–0570; Directorate Identifier 2011–NM–014–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 based on 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

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2011–0006, dated January 17, 2011 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> Since 1984, the design of the hydraulic accumulator installed on all the affected Airbus types has changed. The Part Number (P/N) remained the same, but the manufacturer did not record the serial number of the part that was the first to be manufactured to the changed design specification.
>
> The new design hydraulic accumulator is manufactured with 2 pieces unit welded, instead of 4 pieces unit with 3 welds (old design) as pictured in Appendix 1 of this [EASA] AD. The welding process of the new design hydraulic accumulator provides a higher strength shell material and more reliability.
>
> A recent analysis conducted by the manufacturer showed a particular risk for explosive failure of the old design hydraulic accumulator.
>
> This condition, if not detected and corrected, might, for some aeroplane installations, lead to damage to all three hydraulic circuits, possibly resulting in loss of control of the aeroplane or could, for certain other aeroplane installations, lead to an undetected fire in the wheel bay.
>
> For the reasons explained above, this [EASA] AD requires a one time detailed visual inspection to identify the old designed accumulators installed on certain hydraulic systems, the replacement of those accumulators by new designed accumulators and, irrespective of findings, the installation of warning placards to avoid installation of old designed accumulators on the affected hydraulic systems.

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

Relevant Service Information

Airbus has issued the service bulletins identified in the following table. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

TABLE—SERVICE INFORMATION

Airbus mandatory service bulletin—	Revision—	Dated—
A300–29–0126, including Appendices 01 and 02	01	October 12, 2010.
A300–29–0127	Original	August 12, 2010.
A300–29–6063, including Appendix 01	Original	August 12, 2010.
A300–29–6064	Original	August 12, 2010.
A310–29–2099, including Appendix 01	Original	August 12, 2010.
A310–29–2100	Original	August 12, 2010.

FAA's Determination and Requirements of This Proposed AD

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

Differences Between This AD and the MCAI or Service Information

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

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

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 184 products of U.S. registry. We also estimate that it would take about 7 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $197 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $145,728, or $792 per product.

In addition, we estimate that any necessary follow-on actions would take about 5 work-hours and require parts costing $10,700, for a cost of $11,125 per product. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures

the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, 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 AD:

Airbus: Docket No. FAA–2011–0570; Directorate Identifier 2011–NM–014–AD.

Comments Due Date

(a) We must receive comments by August 8, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to the products identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD, certificated in any category, all manufacturer serial numbers.

(1) Model A300 B2–1A, B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.

(2) Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes.

(3) Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes; A300 B4–605R and B4–622R airplanes; A300 F4–605R and F4–622R airplanes; and A300 C4–605R Variant F airplanes.

Subject

(d) Air Transport Association (ATA) of America Code 29: Hydraulic power.

Reason

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

A recent analysis conducted by the manufacturer showed a particular risk for explosive failure of the * * * hydraulic accumulator.

This condition, if not detected and corrected, might, for some aeroplane installations, lead to damage to all three hydraulic circuits, possibly resulting in loss of control of the aeroplane or could, for certain other aeroplane installations, lead to an undetected fire in the wheel bay.

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspection, Replacement, and Placard Installation

(g) Within 30 months or 6,000 flight hours after the effective date of this AD, whichever occurs first: Do a detailed inspection of each type 5 hydraulic accumulator, part number (P/N) 3059103–1, P/N 3059103–2, P/N 3059103–8, and P/N 3059103–9, to determine if an old design accumulator (i.e., pre-1984) is installed on any affected hydraulic circuit indicated in table 1 of this AD, as applicable, in accordance with the Accomplishment Instructions of the applicable Airbus mandatory service bulletin identified in table 2 of this AD.

TABLE 1—APPLICABLE HYDRAULIC CIRCUITS

Airbus model	Hydraulic circuit
A300 airplanes pre-modification 02447.	Blue and Green.
A300 airplanes post-modification 02447.	Blue.
A300–600 airplanes	Blue.
A310 airplanes	Green.

TABLE 2—APPLICABLE SERVICE INFORMATION

Airbus mandatory service bulletin—	Revision —	Dated —
A300–29–0126 (for Model A300 airplanes)	01	October 12, 2010.
A300–29–6063 (for Model A300–600 airplanes)	Original	August 12, 2010.
A310–29–2099 (for Model A310 airplanes)	Original	August 12, 2010.

(h) If, during any detailed inspection required by paragraph (g) of this AD, an old design hydraulic accumulator (*i.e.,* pre-1984) is found installed on any affected hydraulic circuit as indicated in table 1 of this AD, as applicable to airplane model, before further flight replace each affected old design accumulator with a new design accumulator, in accordance with the Accomplishment Instructions of the applicable Airbus mandatory service bulletin identified in table 2 of this AD.

(i) Before further flight after accomplishing the inspection required by paragraph (g) of this AD: Install a placard at the designated location of any affected hydraulic circuit indicated in table 1 of this AD, as applicable to airplane model, in accordance with the Accomplishment Instructions of the applicable Airbus mandatory service bulletin identified in table 3 of this AD.

TABLE 3—OTHER APPLICABLE SERVICE INFORMATION

Airbus Mandatory Service Bulletin—	Dated—
A300–29–0127	August 12, 2010.
A300–29–6064	August 12, 2010.
A310–29–2100	August 12, 2010.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, 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 International Branch, send it to ATTN: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2125; fax (425) 227–1149. Information may be e-mailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* 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. The AMOC approval letter must specifically reference this AD.

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

Related Information

(k) Refer to MCAI European Aviation Safety Agency (EASA) Airworthiness Directive 2011–0006, dated January 17, 2011; and the service bulletins identified in table 4 of this AD; for related information.

TABLE 4—RELATED SERVICE INFORMATION

Airbus Mandatory Service Bulletin—	Revision—	Dated—
A300–29–0126	01	October 12, 2010.
A300–29–0127	Original	August 12, 2010.
A300–29–6063	Original	August 12, 2010.
A300–29–6064	Original	August 12, 2010.
A310–29–2099	Original	August 12, 2010.
A310–29–2100	Original	August 12, 2010.

Issued in Renton, Washington, on June 10, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–15535 Filed 6–21–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0571; Directorate Identifier 2010–NM–263–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Model 747SP Series 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 products listed above. This proposed AD would require replacing or modifying the upper and lower rudder power control modules (PCM). This proposed AD was prompted by a report of a rudder hard-over event on a Model 747–400 series airplane, caused by a rudder PCM manifold cracking and separating in the area of the yaw damper cavity end-cap. We are proposing this AD to prevent a failure of the lower or upper rudder PCM manifold, which could result in a hard-over of the rudder surface leading to an increase in pilot workload and a possible high-speed runway excursion upon landing.

DATES: We must receive comments on this proposed AD by August 8, 2011.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* 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 Boeing Commercial Airplanes, *Attention:* Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; e-mail *me.boecom@boeing.com;* Internet *https://www.myboeingfleet.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. 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;* 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: Marie Hogestad, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; *phone:* 425–917–6418; *fax:* 425–917–6590; *e-mail: marie.hogestad@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–2011–0571; Directorate Identifier 2010–NM–263–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

We received a report from an operator of a Model 747–400 series airplane of a lower rudder hard-over event caused by a lower rudder PCM manifold cracking and separating in the area of the yaw damper cavity end-cap. This allowed the yaw damper sleeve to shift, giving the system a lower rudder left input (beyond the yaw damper authority).

Yaw damper authority is limited to +/− 4 degrees of rudder command. The failure removed the yaw damper end stop and allowed the yaw damper input to exceed the maximum design yaw damper authority. Although commanding full retract, pilot pedal inputs were ineffective in moving the lower rudder back to the right. We also received three additional reports of cracking in the rudder PCM manifold. These events did not result in a hard-over, but created the need for a retention feature solution specified in AD 2008–13–03, Amendment 39–15566, for Model 747–400, –400D, and –400F series airplanes. Upon investigation, it was determined that the Model 747SP fleet could be susceptible to the same failure because they use the same manifold sub-assembly as the Model 747–400 series airplanes. Cracking in a rudder PCM manifold, if not corrected, could result in a failure of the upper or lower rudder PCM manifold, which could result in a hard-over of the rudder surface leading to an increase in pilot workload and a possible high-speed runway excursion upon landing.

Relevant Service Information

We reviewed Boeing Alert Service Bulletin 747–27A2497, dated September 30, 2010. The service information describes procedures for either replacing the upper and lower rudder PCMs having Boeing part number (P/N) 60B80093–3 (Parker P/N 241700–1005) or Boeing P/N 60B80093–4 (Parker P/N 241700–1007), with new rudder PCMs having Boeing P/N 60B80093–104 (Parker P/N 241700–9007); or modifying the upper and lower rudder PCMs having Boeing P/N 60B80093–3 (Parker P/N 241700–1005) or Boeing P/N 60B80093–4 (Parker P/N 241700–1007) by replacing the access cap with a two piece cap that includes a retention feature for the yaw damper modulating piston assembly in the rudder PCM.

Boeing Alert Service Bulletin 747–27A2497, dated September 30, 2010, refers to Parker Service Bulletin 241700–27–333, dated January 26, 2010, as an additional source of guidance for modifying the upper and lower rudder PCMs provided in Option 2 of Work Packages 1 and 2 of Boeing Alert Service Bulletin 747–27A2497, dated September 30, 2010.

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.

Costs of Compliance

We estimate that this proposed AD affects 7 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
Replace rudder PCM (P/N 241700–1007)	11 work-hours × $85 per hour = $935	$5,856	$6,791	$47,537
Replace rudder PCM (P/N 241700–1005)	11 work-hours × $85 per hour = $935	8,568	9,503	66,521
Modify rudder PCM (P/N 241700–1007)	3 work-hours × $85 per hour = $255	1,374	1,629	11,403
Modify rudder PCM (P/N 241700–1005)	3 work hours × $85 per hour = $255	4,086	4,341	30,387

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

(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–2011–0571; Directorate Identifier 2010–NM–263–AD.

Comments Due Date

(a) We must receive comments by August 8, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all The Boeing Company Model 747SP series airplanes, certificated in any category.

Subject

(d) Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 27, Flight Controls.

Unsafe Condition

(e) This AD was prompted by a report of a rudder hard-over event on a Model 747–400 series airplane, caused by a rudder power control module (PCM) manifold cracking and separating in the area of the yaw damper cavity end-cap. We are issuing this AD to prevent a failure of the lower or upper rudder PCM manifold, which could result in a hard-over of the rudder surface leading to an increase in pilot workload and a possible high-speed runway excursion upon landing.

Compliance

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

Replace or Modify Rudder PCMs

(g) Within 24 months or 8,400 flight hours after the effective date of this AD, whichever occurs first, do the replacement specified in paragraph (g)(1) of this AD or the modification specified in paragraph (g)(2) of this AD for the upper and lower rudder PCMs, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–27A2497, dated September 30, 2010.

(1) Replace any rudder PCM having Boeing part number (P/N) 60B80093–3 (Parker P/N 241700–1005) or Boeing P/N 60B80093–4 (Parker P/N 241700–1007) with rudder PCM having Boeing P/N 60B80093–104 (Parker P/N 241700–9007).

(2) Modify the rudder PCM having Boeing P/N 60B80093–3 (Parker P/N 241700–1005) or Boeing P/N 60B80093–4 (Parker P/N 241700–1007).

Note 1: Boeing Alert Service Bulletin 747–27A2497, dated September 30, 2010, refers to Parker Service Bulletin 241700–27–333, dated January 26, 2010, as an additional source of guidance for modifying the upper and lower rudder PCM manifold access caps provided in Option 2 of Work Packages 1 and 2 of Boeing Alert Service Bulletin 747–27A2497, dated September 30, 2010.

Parts Installation

(h) As of the effective date of this AD, no person may install a rudder PCM having Boeing P/N 60B80093–3 (Parker P/N 241700–1005) or Boeing P/N 60B80093–4 (Parker P/N 241700–1007), on any airplane.

Alternative Methods of Compliance (AMOCs)

(i)(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 the Related Information section of this AD. Information may be e-mailed 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.

Related Information

(j) For more information about this AD, contact Marie Hogestad, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; *telephone:* 425–917–6418; *fax:* 425–917–6590; *e-mail: marie.hogestad@faa.gov.*

(k) For service information identified in this AD, contact Boeing Commercial Airplanes, *Attention:* Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; e-mail *me.boecom@boeing.com*; Internet *https://www.myboeingfleet.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington on June 14, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–15536 Filed 6–21–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0572; Directorate Identifier 2011–NM–009–AD]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace Corporation Model GV and GV–SP 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 products listed above. This proposed AD would require inspecting to determine whether a third Halon fire extinguisher bottle is installed in the auxiliary power unit (APU) fragment impact zone, revising the limitations section of the airplane flight manual to add restrictions for APU usage for certain airplanes having a third fire extinguisher bottle, and removing the third fire extinguisher bottle from certain airplanes. This proposed AD was prompted by notification from the airplane manufacturer that the third fire extinguisher bottle is mounted in a small-fragment impact zone. We are proposing this AD to prevent penetration of the bottle by fragments released due to a failure of the APU rotor system. The bottle could rupture and cause substantial damage to primary airframe structure and primary flight controls.

DATES: We must receive comments on this proposed AD by August 8, 2011.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* 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 Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, Georgia 31402–2206; telephone 800–810–4853; fax 912–965–3520; e-mail pubs@gulfstream.com; Internet *http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. 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;* 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: Sanford Proveaux, Aerospace Engineer, Continued Operational Safety and Certificate Management Branch, ACE–102A, FAA, Atlanta Aircraft Certification Office (ACO) 1701 Columbia Avenue, College Park, Georgia 30337; *phone:* 404–474–5566; *fax:* 404–474–5606; *e-mail: sanford.proveaux@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–2011–0572; Directorate Identifier 2011–NM–009–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

We have received reports from Gulfstream that the third Halon bottle (third fire extinguisher bottle) is mounted in the auxiliary power unit (APU) small-fragment impact zone (rotor burst zone). Some operators might have installed this third fire extinguisher bottle in accordance with Supplemental Type Certificate ST01822AT–D; other operators might have installed the bottle under FAA approval means other than the supplemental type certificate. The bottle is mounted in a very confined area surrounded by primary airframe structure that carries the empennage loads. Primary flight controls for pitch and yaw are also routed through the area adjacent to the third fire extinguisher bottle. Failure of the APU rotor system could release fragments that could strike the bottle and cause explosive rupture of the high-pressure Halon bottle, and result in substantial damage to primary airframe structure and primary flight controls.

Related Rulemaking

We previously issued AD 2009–17–01, Amendment 39–15991 (74 FR 40061, August 11, 2009), for all Model GV airplanes and certain Model GV–SP airplanes (and other Gulfstream airplanes). That AD requires, for certain airplanes, an inspection for sealant applied to the exterior of the APU enclosure (firewall), and, for certain airplanes, a revision of the airplane flight manual to prohibit operation of the APU during certain ground and flight operations. That AD was issued to prevent the flammable sealant from igniting the exterior surfaces of the firewall under certain anomalous conditions such as an APU failure or APU compartment fire, which could result in propagation of an uncontained fire to other critical areas of the airplane.

We are considering revising AD 2009–17–01 to provide an optional terminating action (modification of the APU enclosure), which would allow removal of the APU limitations after the requirements of this new AD have been met.

Relevant Service Information

We reviewed Gulfstream V Alert Customer Bulletin 30A (for Model GV airplanes) Gulfstream G500 Alert Customer Bulletin 10A (for Model GV–SP airplanes); and Gulfstream G550 Alert Customer Bulletin 10A (for Model GV–SP airplanes), all dated December 20, 2010, all including Gulfstream GV/GV–SP Airplane Flight Manual (AFM) Supplement CE51 628M001, Revision A, dated December 20, 2010, to the Gulfstream GV and GV–SP AFMs. These customer bulletins describe procedures for inspecting to determine whether a third fire extinguisher bottle is installed for engines, and, if so, determining whether the third bottle is installed as a spare or in a dedicated configuration. These bulletins also describe procedures for removing the third bottles installed as spares on Model GV and GV–SP airplanes. The Gulfstream GV/GV–SP AFM Supplement CE51 628M001, Revision A, dated December 20, 2010, adds restrictions for APU usage on Model GV and GV–SP airplanes having a third bottle in a dedicated or non-dedicated (spare) configuration.

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 these same type designs.

Proposed AD Requirements

This proposed AD requires accomplishing the actions specified in the service information described previously.

Certain airplanes have a third Halon fire extinguisher bottle carried as a spare. These ''spare'' bottles are not connected to the aircraft fire suppression system electrical or plumbing provisions. In these cases, the bottle can be easily removed without affecting the aircraft fire suppression system. Operators can also leave the spare bottle installed, but must implement the revised APU operating limitations in this case. In some Model GV airplanes only, the third Halon fire extinguisher bottle is a functioning part of the aircraft fire suppression system. In these cases the bottle must remain installed in the airplane, and the revised APU operating limitations must be implemented.

Interim Action

We consider this proposed AD interim action. The manufacturer is currently developing a modification that will address the unsafe condition identified in this proposed AD. Once this modification is developed, approved, and available, we might consider additional rulemaking.

Costs of Compliance

We estimate that this proposed AD affects 1,000 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
Inspection	1 work-hour × $85 per hour = $85	$0	$85	$85,000

We estimate the following costs to do any necessary actions that would be required based on the results of the proposed inspection.

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
AFM revision	1 work-hour × $85 per hour = $85	$0	$85 (about 70 GV/GV–SP airplanes).
Bottle removal	1 work-hour × $85 per hour = $85	$0	$85 (about 30 GV-SP airplanes).

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

(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):

Gulfstream Aerospace Corporation: Docket No. FAA–2011–0572; Directorate Identifier 2011–NM–009–AD.

Comments Due Date

(a) We must receive comments by August 8, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to the Gulfstream Aerospace Corporation airplanes, certificated in any category, identified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Model GV airplanes having serial numbers (S/Ns) 501 and subsequent.

(2) Model GV–SP airplanes having S/Ns 5001 through 5308 inclusive.

Subject

(d) Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 2621, Fire bottle-fixed.

Unsafe Condition

(e) This AD was prompted by notification from the airplane manufacturer that the third fire extinguisher bottle is mounted in a small-fragment impact zone. We are issuing this AD to prevent penetration of the bottle by fragments released due to a failure of the auxiliary power unit (APU) rotor system. The bottle could rupture and cause substantial damage to primary airframe structure and primary flight controls.

Compliance

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

Inspection

(g) *For all airplanes:* Within 21 days after the effective date of this AD, or before removing the APU flight restrictions required by AD 2009–17–01, Amendment 39–15991, whichever occurs first, inspect to determine whether a third Halon fire extinguisher bottle for engines is installed in the APU fragment impact zone (rotor fragment impact zone), in accordance with the Accomplishment Instructions of the applicable Gulfstream alert customer bulletin identified in table 1 of this AD.

TABLE 1—APPLICABLE GULFSTREAM ALERT CUSTOMER BULLETINS

For Model—	Use—	Which includes—	To the—
GV airplanes	Gulfstream V Alert Customer Bulletin 30A, dated December 20, 2010.	Gulfstream GV/GV–SP Airplane Flight Manual (AFM) Supplement CE51 628M001, Revision A, dated December 20, 2010.	Gulfstream GV AFM.
GV–SP (G500) airplanes	Gulfstream G500 Alert Customer Bulletin 10A, dated December 20, 2010.	Gulfstream GV/GV–SP AFM Supplement CE51 628M001, Revision A, dated December 20, 2010.	Gulfstream GV–SP AFM.
GV–SP (G550) airplanes	Gulfstream G550 Alert Customer Bulletin 10A, dated December 20, 2010.	Gulfstream GV/GV–SP AFM Supplement CE51 628M001, Revision A, dated December 20, 2010.	Gulfstream GV–SP AFM.

(1) If the third fire extinguisher bottle is not installed, no further work is required by this paragraph.

(2) For Model GV airplanes in which the third fire extinguisher bottle is installed as a dedicated APU fire bottle configuration, as defined in Gulfstream V Alert Customer Bulletin 30A, dated December 20, 2010 (as a functioning part of the aircraft fire suppression system): Before further flight, revise the Limitations section of the Gulfstream GV AFM to include the information in Gulfstream GV/GV–SP AFM Supplement CE51 628M001, Revision A, dated December 20, 2010 (which is included in Gulfstream V Alert Customer Bulletin 30A, dated December 20, 2010). This AFM supplement adds restrictions for APU usage. Operate the airplane thereafter according to the limitations in this AFM supplement.

Note 1: This may be done by inserting a copy of Gulfstream GV/GV–SP AFM Supplement CE51 628M001, Revision A, dated December 20, 2010, in the applicable AFM. When information in this AFM supplement has been included in general revisions of the applicable AFM, the general revisions may be inserted in the applicable AFM, provided the relevant information in the general revision is identical to that in Gulfstream GV/GV–SP AFM Supplement CE51 628M001, Revision A, dated December 20, 2010, and that AFM supplement may be removed.

(3) For Model GV and GV–SP airplanes in which the third fire extinguisher bottle is installed as a spare fire bottle configuration (not connected to the airplane's electrical or fire suppression systems), as defined in the applicable Gulfstream alert customer bulletin identified in table 1 of this AD: Do the actions required by paragraph (g)(3)(i) or (g)(3)(ii) of this AD.

(i) Before further flight, remove the bottle, in accordance with the Accomplishment Instructions of the applicable Gulfstream alert customer bulletin identified in table 1 of this AD.

(ii) Before further flight, revise the limitations section of the applicable Gulfstream AFM specified in table 1 of this AD to include the information in Gulfstream GV/GV–SP AFM Supplement CE51 628M001, Revision A, dated December 20, 2010. This AFM supplement adds restrictions for APU usage. Operate the airplane thereafter according to the limitations in that AFM supplement.

Note 2: This may be done by inserting a copy of Gulfstream GV/GV–SP AFM Supplement CE51 628M001, Revision A, dated December 20, 2010, in the applicable AFM. When information in this AFM supplement has been included in general revisions of the applicable AFM, the general revisions may be inserted in the applicable AFM, provided the relevant information in the general revision is identical to that in Gulfstream GV/GV–SP AFM Supplement CE51 628M001, Revision A, dated December 20, 2010, and that AFM supplement may be removed.

Credit for Actions Accomplished in Accordance With Previous Service Information

(h) Actions accomplished before the effective date of this AD in accordance with Gulfstream V Alert Customer Bulletin 30 (for Model GV airplanes), dated December 6, 2010, including Gulfstream GV AFM Supplement CE51 628M001, dated November 18, 2010, to the Gulfstream GV AFM; or Gulfstream G550 (for Model GV–SP airplanes) or G500 (for Model GV–SP airplanes) Alert Customer Bulletin 10, both dated December 6, 2010; are acceptable for compliance with the corresponding actions required by paragraph (g) of this AD.

Parts Installation

(i) As of the effective date of this AD, no person may install a third fire extinguisher bottle in the APU fragment impact zone (rotor fragment impact zone) of any airplane.

No Reporting

(j) Although Gulfstream V Alert Customer Bulletin 30A (for Model GV airplanes), Gulfstream G500 Alert Customer Bulletin 10A (for Model GV–SP airplanes), and Gulfstream G550 Alert Customer Bulletin 10A (for Model GV–SP airplanes); all dated December 20, 2010, all including Gulfstream GV/GV–SP AFM Supplement CE51 628M001, Revision A, dated December 20, 2010, to the Gulfstream GV, and GV–SP AFMs; specify to submit certain information to the manufacturer, this AD does not include that requirement.

Special Flight Permit

(k) 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), may be issued to operate the airplane to a location where the requirements of this AD can be accomplished, provided the following conditions are met:

(1) If an airplane is grounded due to a single generator failure, the APU may be operated during a ferry flight, provided no passengers are carried.

(2) Only the minimum required flight crew is allowed on any ferry flight.

Alternative Methods of Compliance (AMOCs)

(l)(1) The Manager, Atlanta 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 the Related Information section 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.

Related Information

(m) For more information about this AD, contact Sanford Proveaux, Aerospace Engineer, Continued Operational Safety and Certificate Management Branch, ACE–102A, FAA, Atlanta Aircraft Certification Office (ACO) 1701 Columbia Avenue, College Park, Georgia 30337; telephone 404–474–5566; fax 404–474–5606; *sanford.proveaux@faa.gov.*

(n) For service information identified in this AD, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, Georgia 31402–2206; telephone 800–810–4853; fax 912–965–3520; e-mail *pubs@gulfstream.com;* Internet *http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington on June 10, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–15537 Filed 6–21–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0639; Directorate Identifier 2011–CE–016–AD]

RIN 2120–AA64

Airworthiness Directives; Piper Aircraft, Inc. Models PA–24, PA–24–250, and PA–24–260 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 products listed above. This proposed AD would require either replacement of the stabilator horn assembly or repetitive inspection of the stabilator horn assembly for corrosion or cracks with replacement of the stabilator horn assembly if any corrosion or cracks are found. This proposed AD was prompted by reports of cracks developing in the stabilator horn assembly. We are proposing this AD to detect and correct corrosion or cracks in the stabilator horn assembly. Corrosion or cracks could lead to failure of the stabilator horn. Consequently, failure of the stabilator horn could lead to a loss of pitch control in flight.

DATES: We must receive comments on this proposed AD by August 8, 2011.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* 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 Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, Florida 32960; telephone: (772) 567–4361; fax: (772) 978–6573; Internet: *http://www.newpiper.com/company/publications.asp.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust St., Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this 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: Gregory K. Noles, Aerospace Engineer, FAA, Atlanta Aircraft Certification Office, 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474–5551; fax: (404) 474–5606; e-mail: *gregory.noles@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–2011–0639; Directorate Identifier 2011–CE–016–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

We issued Special Airworthiness Information Bulletin (SAIB) CE–04–88, dated September 15, 2004. This SAIB alerted owners and operators of Piper Aircraft, Inc. (Piper) Models PA–23, PA–24, PA–30, and PA–39 airplanes of potential corrosion of the stabilator torque tube, attach fittings, and attaching fasteners and recommended inspections of these parts. Based on the information available at issuance of this SAIB, the FAA had determined that an unsafe condition did not exist under 14 CFR part 39.

After reviewing service data for corrosion on the stabilator torque tubes, Piper issued Piper Service Bulletin No. 1160, dated December 26, 2005. This service information is for stabilator torque tube assembly inspection. We then received reports of cracks found in the stabilator horn, part number (P/N) 20397–00, during maintenance inspections per SAIB CE–04–88 or Service Bulletin 1160.

With FAA assistance, the National Institute for Aviation Research (NIAR) investigated and concluded the root cause of the stabilator horn cracking was stress corrosion.

We found two service difficulty reports for this safety issue. In parallel, the International Comanche Society (ICS) surveyed operators and provided additional service data. The ICS survey included approximately 80 targeted inspections and found 18 incidences of stabilator horn cracking, with all incidences occurring on Models PA–24 and PA–24–250 airplanes. The same configuration of horn and torque assembly exists on Model PA–24–260 airplanes.

This condition, if not corrected, could result in failure of the stabilator horn. Consequently, failure of the stabilator horn could lead to a loss of pitch control in flight.

Relevant Service Information

We reviewed Piper Aircraft, Inc. Service Bulletin No. 1189, dated April 29, 2010. The service information describes procedures for stabilator horn assembly inspection.

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 either replacement of the stabilator horn assembly or repetitive inspection of the stabilator horn assembly for corrosion or cracks with replacement of the stabilator horn assembly if any corrosion or cracks are found.

Differences Between the Proposed AD and the Service Information

The service information requires an initial inspection of the stabilator horn assembly upon reaching the initial 1,000 hours time-in-service (TIS), with a repetitive inspection every 100 hours TIS thereafter. After installation of a new stabilator horn assembly, the inspection cycle starts over with an initial inspection at 1,000 hours TIS since the new stabilator horn assembly was installed with the 100-hour TIS repetitive inspections thereafter.

This proposed AD requires either one of the following options: (1) An initial inspection of the stabilator horn assembly upon reaching 1,000 hours TIS or within 100 hours TIS after the effective date of the AD, whichever occurs later, with repetitive inspections every 500 hours TIS or 3 years, whichever occurs first; or (2) replacement of the stabilator horn assembly upon reaching 1,000 hours TIS or within the next 100 hours TIS after the effective date of this AD, whichever occurs later. After replacement of the stabilator horn assembly, within 1,000 hours TIS or 10 years, whichever occurs first, the stabilator horn assembly must be replaced or be initially inspected and start the inspection cycle in option 1.

The service information applies to Piper Models PA–24, PA–24–250, PA–24–260, PA–24–400, PA–30, and PA–39 airplanes. We only have service history on Models PA–24 and PA–24–250 airplanes.

While there is no service history of this unsafe condition on Model PA–24–260 airplanes, we are including it in the AD because it is an identical configuration to Models PA–24 and PA–24–250 airplanes for the horn and torque tube.

There is no service history of this unsafe condition on the Models PA–24–400, PA–30, and PA–39 airplanes, including inspections from the ICS operator survey. Also, these models have a thicker torque tube, which reduces clamp-up forces; clamp-up forces are a key factor of the stress corrosion cracking. Therefore, we are not including the Models PA–24–400,

PA–30, and PA–39 airplanes in the applicability of this AD.

Costs of Compliance

We estimate that this proposed AD affects 3,100 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
Stabilator horn assembly inspection	12 work-hours × $85 per hour = $1,020	Not applicable	$1,020	$3,162,000

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of airplanes that might need this replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Stabilator horn assembly replacement	12 work-hours × $85 per hour = $1,020	$572	$1,592

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

(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):

Piper Aircraft, Inc.: Docket No. FAA–2011–0639, Directorate Identifier 2011–CE–016–AD.

Comments Due Date

(a) We must receive comments by August 8, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to the following Piper Aircraft, Inc. airplanes, certificated in any category:

(1) Model PA–24, serial numbers (SNs) 24–1 through 24–3687;

(2) Model PA–24–250, SNs 24–1, 24–103 through 24–3687; and

(3) Model PA–24–260, SNs 24–3642 and 24–4000 through 24–5034.

Subject

(d) Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 27: Flight Controls.

Unsafe Condition

(e) This AD was prompted by reports of cracks developing in the stabilator horn assembly. We are issuing this AD to detect and correct corrosion or cracks in the stabilator horn assembly. Corrosion or cracks could lead to failure of the stabilator horn. Consequently, failure of the stabilator horn could lead to a loss of pitch control in flight.

Compliance

(f) Comply with this AD following Piper Aircraft, Inc. Service Bulletin No. 1189, dated April 29, 2010, within the compliance times specified in this AD, unless already done (does not eliminate the repetitive actions of this AD).

Inspection/Replacement

(g) When the stabilator horn assembly reaches a total of 1,000 hours time-in-service (TIS) or within the next 100 hours TIS after the effective date of this AD, whichever occurs later, do either of the following actions:

(1) Initially inspect the stabilator horn assembly for corrosion or cracks. Repetitively thereafter inspect at intervals not to exceed 500 hours TIS or 3 years, whichever occurs first; or

(2) Replace the stabilator horn assembly with a new stabilator horn assembly. Repetitively thereafter replace the stabilator horn assembly with a new stabilator horn assembly within the next 1,000 hours TIS

after the last replacement or within the next 10 years after the last replacement, whichever occurs first.

(h) If any corrosion or cracks are found during any of the inspections required in paragraph (g)(1) of this AD, before further flight, you must replace the stabilator horn assembly with a new stabilator horn assembly. After the new stabilator horn assembly reaches a total of 1,000 hours TIS or within the next 10 years after the last replacement, whichever occurs first, you must do either of the actions required in paragraphs (g)(1) or (g)(2) of this AD.

(i) You may at any time replace the stabilator horn assembly with a new stabilator horn assembly, provided no corrosion or cracks were found during an inspection that would require replacement before further flight. After the new stabilator horn assembly reaches a total of 1,000 hours TIS or within the next 10 years after the last replacement, whichever occurs first, you must do either of the actions required in paragraphs (g)(1) or (g)(2) of this AD.

(j) If you replace the stabilator horn assembly as specified in paragraph (g)(2) of this AD, after the new stabilator horn assembly reaches a total of 1,000 hours TIS or within the next 10 years after the last replacement, whichever occurs first, you may begin the inspection requirements of paragraph (g)(1) instead of the repetitive replacement requirements of paragraph (g)(2).

Note: Piper Aircraft, Inc. Service Bulletin No. 1160, dated December 26, 2005; Special Airworthiness Information Bulletin CE–04–88, dated September 15, 2004; and AD 74–13–03, Amendment 39–2588 (41 FR 17371, April 26, 1976) are related to this AD action. For the attached torque tube, you may consider combining that inspection with the requirements of this AD.

Special Flight Permit

(k) Special flight permits are permitted with the following limitation: flight with known cracks is prohibited.

Alternative Methods of Compliance (AMOCs)

(l)(1) The Manager, Atlanta 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 the Related Information section 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.

Related Information

(m) For more information about this AD, contact Gregory K. Noles, Aerospace Engineer, FAA, Atlanta ACO, 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474–5551; fax: (404) 474–5606; e-mail: *gregory.noles@faa.gov.*

(n) For service information identified in this AD, contact Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, Florida 32960; telephone: (772) 567–4361; fax: (772) 978–6573; Internet: *http://www.newpiper.com/company/publications.asp.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust St., Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri on June 16, 2011.

John Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–15543 Filed 6–21–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0569; Directorate Identifier 2010–NM–240–AD]

RIN 2120–AA64

Airworthiness Directives; BAE SYSTEMS (OPERATIONS) LIMITED Model BAe 146 and Avro 146–RJ 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 products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

BAE Systems have received reports of in-service failure of the Main Landing Gear (MLG) shock absorber lower attachment pin.

* * * * *

This condition, if not detected and corrected, could lead to a MLG collapse on the ground or during landing and consequently damage to the aeroplane or injury to the occupants.

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

DATES: We must receive comments on this proposed AD by August 8, 2011.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–40, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For BAE SYSTEMS (OPERATIONS) LIMITED service information identified in this proposed AD, contact BAE SYSTEMS (OPERATIONS) LIMITED, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; e-mail *RApublications@baesystems.com;* Internet *http://www.baesystems.com/Businesses/RegionalAircraft/index.htm.*

For Messier-Dowty service information identified in this proposed AD, contact Messier Services Americas, Customer Support Center, 45360 Severn Way, Sterling, Virginia 20166–8910; telephone 703–450–8233; fax 703–404–1621; Internet *https://techpubs.services/messier-dowty.com.*

You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. 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;* or in person at the Docket Operations office 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 Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1175; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No.

FAA–2011–0569; Directorate Identifier 2010–NM–240–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 based on 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

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2010–0201, dated October 5, 2010 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> BAE Systems have received reports of in-service failure of the Main Landing Gear (MLG) shock absorber lower attachment pin.
>
> Investigation has shown that the pin failures were due to corrosion.
>
> This condition, if not detected and corrected, could lead to a MLG collapse on the ground or during landing and consequently damage to the aeroplane or injury to the occupants.
>
> For the reasons described above, this AD requires repetitive [general visual] inspections [for damage (cracking, corrosion, and exposed material)] of the MLG shock absorber lower attachment pins and replacement, depending on findings.

The replacement, if damage is found, consists of installing serviceable pins. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

BAE SYSTEMS (OPERATIONS) LIMITED has issued Inspection Service Bulletin ISB.32–176, dated November 12, 2009. Messier-Dowty has issued Service Bulletin 146–32–157, including Appendix A, dated February 12, 2009. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

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

Differences Between This AD and the MCAI or Service Information

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

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

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 1 product of U.S. registry. We also estimate that it would take about 2 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $170 per product.

In addition, we estimate that any necessary follow-on actions would take about 2 work-hours and require parts costing $14,000, for a cost of $14,170 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, 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 AD:

BAE Systems (Operations) Limited: Docket No. FAA–2011–0569; Directorate Identifier 2010–NM–240–AD.

Comments Due Date

(a) We must receive comments by August 8, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to BAE SYSTEMS (OPERATIONS) LIMITED Model BAe 146–100A, –200A, and –300A airplanes; and Avro 146–RJ70A, 146–RJ85A, and 146–RJ100A airplanes; certificated in any category; all serial numbers.

Subject

(d) Air Transport Association (ATA) of America Code 32: Landing gear.

Reason

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

BAE Systems have received reports of in-service failure of the Main Landing Gear (MLG) shock absorber lower attachment pin.

* * * * *

This condition, if not detected and corrected, could lead to a MLG collapse on the ground or during landing and consequently damage to the aeroplane or injury to the occupants.

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspections

(g) Within 4,000 flight cycles or 2 years after the effective date of this AD, whichever occurs first: Do the initial inspection of the MLG shock absorber lower attachment pins in accordance with paragraph 2.C of BAE SYSTEMS (OPERATIONS) LIMITED Inspection Service Bulletin ISB.32–176, dated November 12, 2009; and paragraph 3. of Messier-Dowty Service Bulletin 146–32–157, dated February 12, 2009.

(h) Thereafter, at intervals not to exceed 8,000 flight cycles or 4 years, whichever occurs first, repeat the inspection required by paragraph (g) of this AD.

Corrective Action

(i) If, during any inspection required by paragraphs (g) and (h) of this AD, the chromium plating on the outer diameter of any pin is found cracked, or the base material is exposed, or any corrosion is found on the chromium plating on the outer diameter of any pin, before further flight, replace the pin with a serviceable pin in accordance with paragraph 2.C of BAE SYSTEMS (OPERATIONS) LIMITED Inspection Service Bulletin ISB.32–176, dated November 12, 2009; and paragraph 3. of Messier-Dowty Service Bulletin 146–32–157, dated February 12, 2009.

(j) Replacing the pin, as required by paragraph (i) of this AD, does not constitute a terminating action for the repetitive inspections required by paragraph (h) of this AD.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, 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 International Branch, send it to ATTN: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1175; fax (425) 227–1149. Information may be e-mailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* 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. The AMOC approval letter must specifically reference this AD.

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

Related Information

(l) Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2010–0201, dated October 5, 2010; BAE SYSTEMS (OPERATIONS) LIMITED Inspection Service Bulletin ISB.32–176, dated November 12, 2009; and Messier-Dowty Service Bulletin 146–32–157, dated February 12, 2009; for related information.

Issued in Renton, Washington on June 10, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–15538 Filed 6–21–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Chapter I

[Docket Nos. RM11–24–000 and AD10–13–000]

Third-Party Provision of Ancillary Services; Accounting and Financial Reporting for New Electric Storage Technologies

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of inquiry.

SUMMARY: In this Notice of Inquiry (NOI), the Commission seeks comment on two sets of separate, but related issues. First, we seek comment on ways in which we can facilitate the development of robust competitive markets for the provision of ancillary services from all resource types. Second, the Commission is interested in issues unique to storage devices in light of the role they can play in providing multiple services, including ancillary services. As demonstrated by recent cases that have come before the Commission, there is growing interest in rate flexibility by both purchasers and sellers of ancillary services. A variety of resources are poised to provide ancillary services but may be frustrated from doing so by certain aspects of the Commission's market-based rate policies coupled with a lack of access to the information that could help satisfy the requirements of those policies. Those with an obligation to purchase ancillary services have raised concerns with the availability of those services. In reviewing ways to foster a more robust ancillary services market, the Commission identified certain issues regarding the use of electric storage as an ancillary service resource that warranted consideration. Over time, those issues expanded into more global questions as to the role that electric storage may play in a competitive market, including how electric storage should be compensated for the full range of services it provides under the Federal Power Act, and transparency issues regarding the Commission's current accounting and reporting requirements as applied to electric storage. As such, the Commission seeks comment on: Existing restrictions on third-party provision of ancillary services, irrespective of the technologies used for such provision; and the adequacy of current accounting and reporting requirements as they pertain to the oversight of jurisdictional entities using electric storage devices.

DATES: Comments are due August 22, 2011.

ADDRESSES: You may submit comments, identified by docket number and in accordance with the requirements posted on the Commission's Web site, *http://www.ferc.gov.* Comments may be submitted by any of the following methods:

- *Agency Web Site:* Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format, at *http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail/Hand Delivery:* Commenters unable to file comments electronically must mail or hand deliver an original and copy of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE., Washington, DC 20426. These requirements can be found on the Commission's Web site, *see, e.g.*, the ''Quick Reference Guide for Paper Submissions,'' available at *http://www.ferc.gov/docs-filing/efiling.asp,* or

via phone from Online Support at (202) 502–6652 or toll-free at 1–866–208–3676.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Comment Procedures Section of this document.

FOR FURTHER INFORMATION CONTACT:

Rahim Amerkhail (Technical Information), Office of Energy Policy and Innovation, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8266.

Christopher Handy (Accounting Information), Office of Enforcement, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–6496.

Eric Winterbauer (Legal Information), Office of General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8329.

SUPPLEMENTARY INFORMATION:

Notice of Inquiry

June 16, 2011

1. In this Notice of Inquiry (NOI), the Commission seeks comment on two sets of separate, but related issues. First, we seek comment on ways in which we can facilitate the development of robust competitive markets for the provision of ancillary services from all resource types. Second, the Commission is interested in issues unique to storage devices in light of the role they can play in providing multiple services, including ancillary services. As demonstrated by recent cases that have come before the Commission, there is growing interest in rate flexibility by both purchasers and sellers of ancillary services. A variety of resources are poised to provide ancillary services but may be frustrated from doing so by certain aspects of the Commission's market-based rate policies coupled with a lack of access to the information that could help satisfy the requirements of those policies. Those with an obligation to purchase ancillary services have raised concerns with the availability of those services. In reviewing ways to foster a more robust ancillary services market, the Commission identified certain issues regarding the use of electric storage as an ancillary service resource that warranted consideration. Over time, those issues expanded into more global questions as to the role that electric storage may play in a competitive market, including how electric storage should be compensated for the full range of services it provides under the Federal Power Act, and transparency issues regarding the Commission's current accounting and reporting requirements as applied to electric storage. As such, the Commission seeks comment on: (1) Existing restrictions on third-party provision of ancillary services, irrespective of the technologies used for such provision; and (2) the adequacy of current accounting and reporting requirements as they pertain to the oversight of jurisdictional entities using electric storage devices.

2. More specifically, the Commission is interested in obtaining comments on: (1) Whether revising or replacing the restriction set forth in *Avista Corp.* (referred to as the *Avista* restriction),[1] which prohibits third-party market-based sales of ancillary services to transmission providers seeking to meet their ancillary service obligations under the Open Access Transmission Tariff (OATT), absent a market study showing lack of market power, would help to facilitate the provision of ancillary services, and if so, how to balance that goal with the need to ensure just and reasonable rates; and (2) Whether revising the current accounting and reporting requirements as they pertain to regulatory oversight of jurisdictional entities using storage technologies is necessary.[2] Related to the first inquiry, the Commission also seeks comment on whether the various cost-based compensation methods for frequency regulation that exist in regions outside of the current organized markets could be adjusted to address the same speed and accuracy issues identified in the recently-issued Frequency Regulation Notice of Proposed Rulemaking for organized wholesale energy markets.[3]

I. Background

3. The Commission has initiated numerous actions over the last several decades to foster the development of competitive wholesale energy markets by ensuring non-discriminatory access and comparable treatment of resources in jurisdictional wholesale markets.[4] The Commission most recently proposed to require all independent system operators (ISO) and regional transmission organizations (RTO) to compensate resources that provide frequency regulation in a manner that reflects the resource's performance in order to remedy undue discrimination.[5]

4. As a result of many of these actions, there has been entry not only of competitive generation but also new technologies like electric storage that can provide many of the same services as generation and even transmission. The Commission remains interested in the continued development of competitive markets for all services and in this inquiry considers the development of a more robust ancillary services market and issues unique to storage devices in light of the role they can play in providing multiple services, including ancillary services. We also note that the role electric storage and other new market entrants play in competitive markets is still evolving. With that evolution, the Commission must continue to assess the full value those resources provide to competitive markets and to ensure just and reasonable rates.

5. In addition to the Commission's generic initiatives to further the development of competitive wholesale markets, the Commission has taken action on a case-by-case basis to remove barriers to the entry of new technologies. In certain areas of the country where FERC jurisdictional tariffs included provisions largely designed for thermal resources, and as

[1] *Avista Corp.,* 87 FERC ¶ 61,223 (*Avista), order on reh'g,* 89 FERC ¶ 61,136 (*Avista* Rehearing Order) (1999).

[2] These as well as several other issues were the subject of a Commission staff Notice of Request for Comment (Storage RFC) issued June 11, 2010. This proceeding focuses primarily on issues associated with the pricing of ancillary services and accounting and reporting requirements.

[3] *Frequency Regulation Compensation in the Organized Wholesale Power Markets,* 76 FR 11177 (Mar. 1, 2011), Notice of Proposed Rulemaking, FERC Stats. & Regs. ¶ 32,672 (2011) (Frequency Regulation NOPR).

[4] *See, e.g., Promoting Wholesale Competition Through Open Access Non–Discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities,* Order No. 888, FERC Stats. & Regs. ¶ 31,036, at 31,781 (1996), *order on reh'g,* Order No. 888–A, FERC Stats. & Regs. ¶ 31,048, *order on reh'g,* Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order on reh'g,* Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part sub nom. Transmission Access Policy Study Group* v. *FERC,* 225 F.3d 667 (DC Cir. 2000), *aff'd sub nom. New York* v. *FERC,* 535 U.S. 1 (2002); *Market–Based Rates for Wholesale Sales of Electric Energy, Capacity and Ancillary Services by Public Utilities,* Order No. 697, FERC Stats. & Regs. ¶ 31,252, *clarified,* 121 FERC ¶ 61,260 (2007), *order on reh'g,* Order No. 697–A, FERC Stats. & Regs. ¶ 31,268, *clarified,* 124 FERC ¶ 61,055, *order on reh'g,* Order No. 697–B, FERC Stats. & Regs. ¶ 31,285 (2008), *order on reh'g,* Order No. 697–C, FERC Stats. & Regs. ¶ 31,291 (2009), *order on reh'g,* Order No. 697–D, FERCStats. & Regs. ¶ 31,305 (2010); *Preventing Undue Discrimination and Preference in Transmission Service,* Order No. 890, FERC Stats. & Regs. ¶ 31,241, *order on reh'g,* Order No. 890–A, FERC Stats. & Regs. ¶ 31,261 (2007), *order on reh'g,* Order No. 890–B, 123 FERC ¶ 61,299 (2008), *order on reh'g,* Order No. 890–C, 126 FERC ¶ 61,228 (2009), *order on reh'g,* Order No. 890–D, 129 FERC ¶ 61,126 (2009); *Wholesale Competition in Regions with Organized Electric Markets,* Order No. 719, FERC Stats. & Regs. ¶ 31,281 (2008); *order on reh'g,* Order No. 719–A, FERC Stats. & Regs. ¶ 31,292 (2009); *order on reh'g,* Order No. 719–B, 129 FERC ¶ 61,252 (2009).

[5] *See supra* note 3.

such presented barriers to the participation of other technologies like electric storage, the Commission has accepted a variety of proposed reforms. For example, Midwest Independent Transmission System Operator (Midwest ISO) and New York Independent System Operator, Inc. (NYISO) both have tariff provisions for managing the energy level of limited energy storage resources (LESRs) providing regulation service.[6] Also under its tariff, NYISO has begun dispatching LESRs first and all other resources on a pro-rata basis.[7] PJM Interconnection, L.L.C. (PJM) has tariff provisions excluding most of the energy used for charging several types of energy storage devices from its definition of station power load.[8] In 2010, the California Independent System Operator Corporation (CAISO) revised the technical requirements for participation in its ancillary services market to allow non-generator resources to be treated on a comparable basis to generation resources.[9]

6. The Commission has also addressed specific proposals for flexibility of the Commission's policies and/or regulations. With regard to the Commission's *Avista* policy, WSPP recently requested waiver of the *Avista* restriction in order to allow market-based rate sales of ancillary services under proposed WSPP master sales agreement Schedules D and E for those sellers that have market-based rate authorization for energy but have not performed market studies for ancillary services or proposed any alternative mitigation measure to ensure just and reasonable ancillary service rates.[10]

7. The Commission has also entertained energy storage proposals by individual developers, some of which seek treatment only as competitive wholesale suppliers, and some of which seek treatment as transmission facilities. When faced with various proposals to use energy storage technologies for jurisdictional purposes, the Commission has analyzed the intended use and capability of storage proposals on a case-by-case basis.[11] Where applicants have sought transmission rate recovery for storage assets, the Commission has also reviewed whether the proposal would result in: (1) Cross-subsidization of any competitive market sales by transmission customers; (2) inappropriate competitive impacts if one type of market participant were permitted to receive jurisdictional transmission ratebase treatment while other market participants are completely at risk in the market; and (3) a level of control in the operation of a storage facility by the RTO or ISO that could jeopardize its independence from market participants. These issues arise when a storage project seeks cost-based transmission rate authorization and proposes to participate in competitive wholesale energy and ancillary service markets. In contrast, where a storage project proposes only to participate in one or more competitive wholesale energy and ancillary service markets, these issues do not arise because there will be no associated cost-based transmission rate for the same storage asset.

8. In light of the growing interest in electric storage, Commission staff in June 2010 issued the Storage RFC to seek comment on a variety of issues including: Alternatives for categorizing and compensating storage services, including how best to develop rate policies that accommodate the flexibility of storage; whether the Avista restriction, which prohibits third-party provision of ancillary services at market-based rates to transmission providers seeking to meet their own ancillary services requirements, can pose an undue barrier to the development of storage facilities and other resources capable of providing ancillary services; and accounting and financial reporting matters as they relate to recovery of costs for electric storage technologies, noting that the Commission's accounting and financial reporting requirements currently do not contain specific accounting[12] and related reporting requirements[13] for new storage technologies. The Storage RFC noted that storage facilities are physically capable of providing a variety of services, including transmission service to unbundled transmission customers, enhancing the value of generation output sold at wholesale, and providing ancillary services.[14]

9. As a result of the information developed thus far through these various efforts, the Commission's inquiry in this proceeding considers, among other things, the application of the Avista policy. We believe that markets for ancillary services may not be developing in all regions of the country. This may be due in part to the nature of ancillary services and the lack of transparent information on the capability of individual resources to provide the various services, thus hindering sellers'' ability in some regions of the country to perform market power studies to demonstrate the lack of market power. This coupled with a growing need for ancillary services to support grid functions in the face of potential changes in the portfolio of generation resources, entry of new technologies seeking to provide the services, and the growing interest of sellers and transmission providers to have flexibility in meeting ancillary services needs prompts this inquiry.

10. We note that there are numerous issues embedded within these broad categories of inquiry and we encourage comment from all interested stakeholders. We further note, however, that we will continue to address additional matters regarding rate treatment and products for electric storage on a case-by-case basis.

II. Discussion

A. Third-Party Provision of Ancillary Services and the Avista Restriction

11. The Commission, in Order No. 888,[15] contemplated the idea of third parties (*i.e.,* parties other than a transmission provider supplying ancillary services pursuant to its OATT obligation) providing ancillary services on other than a cost-of-service basis if such pricing was supported, on a case-by-case basis, by analyses that demonstrated that the seller lacks market power. The Commission in

[6] *See Midwest Indep. Trans. Sys. Operator, Inc.,* 129 FERC ¶ 61,303 (2009); *New York Indep. Sys. Operator, Inc.,* 127 FERC ¶ 61,135 (2009).

[7] *See, e.g., New York Indep. Sys. Operator, Inc.,* 127 FERC ¶ 61,135, at P 7 (2009).

[8] *See PJM Interconnection, L.L.C.,* 132 FERC ¶ 61,203 (2010).

[9] *See California Independent System Operator Corporation,* 132 FERC ¶ 61,211, at P 26 (2010).

[10] *WSPP Inc.*, 134 FERC ¶ 61,169 (2011) (*WSPP*).

[11] *See, e.g., Western Grid Development, LLC,* 130 FERC ¶ 61,056, *reh'g denied,* 133 FERC ¶ 61,029 (2010) (*Western Grid*) and *Nevada Hydro Co.*, 122 FERC ¶ 61,272 (2008) (*Nevada Hydro*).

[12] *Uniform System of Accounts Prescribed for Public Utilities and Licensees Subject to the Provisions of the Federal Power Act* (USofA), 18 CFR part 101.

[13] *Statements and Reports (Schedules),* 18 CFR part 141.

[14] The Storage RFC also sought comment regarding rate treatment alternatives for electric storage technologies depending on the intended use or capability of the facility; possible business models for storage, including stand-alone storage; and new ancillary services products. The Commission will continue to review various proposals relevant to these issues on a case-by-case basis and does not seek further comment on these matters here.

[15] *Promoting Wholesale Competition Through Open Access Non–Discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities,* Order No. 888, FERC Stats. & Regs. ¶ 31,036, at 31,781 (1996), *order on reh'g,* Order No. 888–A, FERC Stats. & Regs. ¶ 31,048, *order on reh'g,* Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order on reh'g,* Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part sub nom. Transmission Access Policy Study Group* v. *FERC,* 225 F.3d 667 (DC Cir. 2000), *aff'd sub nom. New York* v. *FERC,* 535 U.S. 1 (2002).

Order No. 888 and later in *Ocean Vista*[16] offered guidance as to what should be included in a market power study for ancillary services, stating that the guidance was offered for two purposes: (1) To ensure that sellers of ancillary services do not exercise market power; and (2) to further the goal of promoting competition in ancillary service markets.

12. In *Avista,* the Commission discussed in detail the data problems associated with performing a market power study and adopted a policy allowing third-party ancillary service providers that could not perform a market power study to sell certain ancillary services at market-based rates with certain restrictions.[17] Specifically, the Commission allowed a market participant with market-based rate authorization to sell ancillary services at market-based rates to transmission customers that would otherwise purchase ancillary services from a public utility transmission provider. However, the Commission prohibited sales of ancillary services at market-based rates by a third-party supplier in the following situations: (1) Sales To an RTO or an ISO, which has no ability to self-supply ancillary services but instead depends on third parties;[18] (2) to address affiliate abuse concerns, sales to a traditional, franchised public utility affiliated with the third-party supplier, or sales where the underlying transmission service is on the system of the public utility affiliated with the third-party supplier;[19] and (3) sales to a public utility that is purchasing ancillary services to satisfy its own OATT requirements to offer ancillary services to its own customers.[20] The Commission further stated that it was open to considering requests to make ancillary services sales at market-based rates in such circumstances on a case-by-case basis.[21]

13. In the *Avista* Rehearing Order, the Commission clarified that although Avista prohibits third-party ancillary services suppliers from selling to transmission providers in order for transmission providers to meet their own ancillary service requirements, a transmission provider could purchase from a third-party supplier to permit it to offer third-party ancillary services off of its system.[22] The Commission explained:

> We are able to grant blanket authority for flexible pricing only because the price charged by the third-party supplier is disciplined by the obligation of the transmission provider to offer these services under cost-based rates. This discipline could be thwarted if the transmission provider could substitute purchases under non-cost-based rates for its mandatory service obligation.[23]

The Commission concluded that the protection of the ''backstop of cost-based ancillary services from the transmission provider will provide an appropriate and effective safeguard against potential anti-competitive behavior.'' [24]

14. Accordingly, absent market studies showing a lack of market power, *Avista* placed a restriction on third-party market-based sales of ancillary services to utilities seeking to meet their OATT obligations. Under the Commission's *Avista* policy, third-party sellers that want to sell at market-based rates to a transmission provider seeking to meet its OATT ancillary service obligations must perform a market power study; third party sellers that desire to sell ancillary services at market-based rates to entities other than transmission providers may do so without restriction.[25]

15. Recently, WSPP requested waiver of the *Avista* restriction in order to allow market-based rate sales of ancillary services under proposed WSPP master sales agreement Schedules D and E for those sellers that have market-based rate authorization for energy but did not perform market studies for ancillary services or proposed any alternative mitigation measure to ensure just and reasonable ancillary service rates.[26] In support, WSPP stated that the *Avista* restrictions have foreclosed the development of third-party ancillary services markets and relegated transmission providers to provide their own reserves through self-supply.[27] WSPP also argued that there are two reasons why market power studies are feasible in RTO/ISO regions but not elsewhere: (1) Centralized RTO/ISO markets and related access to data ease the way for performance of studies; and (2) RTO/ISOs have ready staffs and funds through which studies are feasible.[28] The Commission rejected WSPP's request as it related to sales by a third-party supplier to satisfy the purchasing transmission provider's own OATT requirements to offer ancillary services to its customers. The Commission explained that:

> (w)hile the Commission wishes to foster entry into ancillary service markets, we also must guard against potential anticompetitive behavior by third-party suppliers who may have market power. We cannot simply assume that no anticompetitive behavior would occur were we to grant WSPP's request.[29]

The Commission noted, however, that it remains open to new approaches to selling reserve services at market-based rates and encouraged WSPP to submit a revised proposal that addresses the Commission's concerns.

16. As indicated both in comments to the Storage RFC and the recent *WSPP* filing that sought waiver of the *Avista* restrictions,[30] market participants are looking for additional flexibility regarding the *Avista* restrictions, partly because the most significant market for ancillary services is likely to be transmission providers seeking to meet their OATT ancillary service

[16] *Ocean Vista Power Generation, L.L.C.,* 82 FERC ¶ 61,114 (1998) (*Ocean Vista*).

[17] The authorization in *Avista* extended to the following four ancillary services: Regulation Service, Energy Imbalance Service, Spinning Reserves, and Supplemental Reserves.

[18] Subsequently, as the Commission recognized in Order No. 697, most RTOs and ISOs developed formal ancillary service markets and performed associated market power studies, thus rendering this component of the *Avista* policy largely superfluous. *See* Order No. 697, FERC Stats. & Regs. ¶ 31,252 at n.1194 and P 1069.

[19] We are not aware of any need to revise this second component of the *Avista* policy.

[20] *Avista,* 87 FERC ¶ 61,223 at n.12.

[21] *Id.* The Commission has granted waiver of the *Avista* restrictions on a case-by-case basis. *See, e.g., NorthWestern Corp. and Powerex Corp.,* 121 FERC ¶ 61,204 (2007) (granting Powerex limited waiver of the prohibition against making sales of ancillary services at market-based rates to public utilities that are purchasing such services to satisfy their own OATT requirements to offer ancillary services to their customers and accepting an agreement between NorthWestern and Powerex following a competitive solicitation under which Powerex will sell regulating reserve services to NorthWestern at market-based rates for a one-year period); *Powerex Corp.,* 125 FERC ¶ 61,179 (2008) (granting Powerex limited waiver of the prohibition from making sales of ancillary services at market-based rates to public utilities that are purchasing such services to satisfy their own OATT requirements to offer ancillary services to their customers and conditionally accepting an agreement between NorthWestern and Powerex following a competitive solicitation under which Powerex will sell regulating reserve services to NorthWestern at market-based rates over a two-year period, subject to extension for an additional year); *NorthWestern Corp.,* 125 FERC ¶ 61,178 (2008) (accepting an agreement between NorthWestern and Public Utility District No. 2 of Grant County, Washington, following a competitive solicitation under which Grant County will sell regulating reserve services to NorthWestern at market-based rates over a two-year period, subject to extension).

[22] *Avista* Rehearing Order, 89 FERC at 61,391.

[23] *Id.*

[24] *Avista,* 87 FERC ¶ 61,136 at 61,883.

[25] Although there is no restriction on these sales, the transmission provider's OATT rate theoretically serves as a check on prices because potential buyers can always resort to OATT service.

[26] *WSPP,* 134 FERC ¶ 61,169 at P 5.

[27] WSPP, Answer, Docket No. ER10–2295–000, at 4 (Filed December 10, 2010).

[28] *Id.* at 5.

[29] *WSPP,* 134 FERC ¶ 61,169 at P 24.

[30] WSPP's request for waiver was rejected by the Commission. *Id.* P 27.

obligations. Furthermore, NorthWestern indicated in a filing before the Commission that it was unable to find sellers of ancillary services when it issued a request for proposals, noting that only two offers were able to satisfy the technical requirements and time commitments set forth in the request for proposals from the 70 entities that received the request for proposals.[31] Several commenters in response to the Storage RFC also argue that experience has proven this restriction to be unnecessary, potentially harmful to both load-serving entities and would-be third-party suppliers of ancillary services, and a barrier to the use of storage technologies to provide ancillary services.[32]

17. As the Commission explained in *WSPP,*[33] the prohibition on third-party ancillary service sales to transmission providers seeking to meet their own ancillary service requirements was designed to address the Commission's concern that the backstop of cost-based ancillary services from the transmission provider would not remain an effective safeguard against anti-competitive behavior by third-party sellers, if the transmission provider's OATT rates were allowed to include a pass through of purchases under non-cost-based rates from third parties who had not performed a market power study.

18. However, we acknowledge the interest in creating a market for certain ancillary services and recognize concerns sellers have about being unable to conduct formal market power studies. We therefore request comment on possible ways of modifying the *Avista* restriction while ensuring just and reasonable rates, including comments on possible reforms to the Commission's market power study requirements and ideas for alternative mitigation to permit rate flexibility. Specifically, we request comment on the following.

1. Market Power Study

19. Concerns regarding the ability of a seller to perform a market power study for ancillary services that were present at the time of *Avista* appear to remain today for sellers in some regions of the country. As such:

a. Is information on individual generating unit frequency regulation, spinning and non-spinning reserve capability publicly available?

b. If the Commission retains the requirement of a formal market power study as described in Order No. 888 and *Ocean Vista* for third party provision of ancillary services to transmission providers, what specific information and tools would be useful to the development of these studies?

c. What are some of the ways/vehicles that the information above can be made publicly available, *e.g.*, Commission reporting requirement or voluntary posting?

d. If commercial sensitivity is an issue, is there an appropriate time lag for making information available?

e. While market power analyses have been performed within the organized wholesale energy markets, are there alternative market power studies, for example that use less granular data, or take other steps like appropriate simplifying assumptions, that could be used in other regions to establish whether a seller of ancillary services has market power?

2. De Minimis Threshold Below Which Market-Based Rates Authorized

20. In lieu of requiring sellers to submit formal market power studies, should the Commission establish a measure of *de minimis* market presence that would justify a grant of market based-rate authority? Specifically:

a. Should the Commission establish a capacity threshold to determine whether an entity has market power, so that an entity that owns or controls less than a threshold amount of capacity would be presumed to lack market power in the market for provision of ancillary services? If so, what would be an appropriate level for this threshold?

b. Alternatively, should the Commission establish a presumption that an entity that provides less than a threshold amount of ancillary services over a defined period lacks market power in the relevant market for such services? If yes, what would be an appropriate level for this threshold? Over what time period(s) should the threshold be established (*e.g.*, annual, hourly, daily)? Would it be appropriate to make new generating units or other resources eligible for this exemption based on their maximum potential sales of ancillary services?

c. Should the threshold be set for individual ancillary services or should it be set for multiple ancillary services that often are good substitutes (*e.g.*, spinning and supplemental reserves)?

d. Would it be appropriate to vary the threshold across different balancing authority areas and/or different regions?

e. Should entities that receive authorization to provide ancillary services at market-based rates based on a *de minimis* presence be subject to a periodic filing requirement and/or a ''change in status'' filing requirement to ensure that they continue to meet the threshold?

3. Alternative Mitigation To Permit Rate Flexibility

21. In lieu of requiring that sellers desiring to make sales to transmission providers submit formal market power studies, are there other measures that could be taken to allow such sales and yet ensure just and reasonable rates for third-party market-based ancillary services? That is, could the Commission replace the *Avista* restriction with some other means of ensuring that the backstop of cost-based ancillary services from the transmission provider will continue to provide an appropriate and effective safeguard against potential anti-competitive behavior?

a. Would ensuring that transmission providers do not automatically pass through the price of any non-cost-based third-party purchases that exceed their OATT rate permit the backstop of cost-based ancillary services from the transmission provider to continue mitigating third-party market power?

b. Alternatively, would it be appropriate to waive the current third-party sales restriction in cases where the purchasing transmission provider voluntarily commits not to pass-through the price of non-cost-based third-party purchases that exceed its OATT rates to its wholesale and native load retail customers? Would such a commitment by the purchasing transmission provider adequately ensure the continued value for third-party market power mitigation of the OATT cost-based rate backstop, while still permitting third-party sales to transmission providers?

c. As another alternative, in recognition that new entrants'' costs may be higher than those reflected in current OATT rates, we seek comment on an explicit price-cap for third-party sales to utilities to serve their OATT ancillary service obligations based on the purchasing utility's Commission-approved OATT rate plus an adder. For example, would an OATT-based cost cap set at 105 percent of the purchasing utility's existing OATT rate be appropriate given the potentially higher costs of new entrants?[34] Would a cap equal to 105 percent of the purchasing transmission provider's OATT rate generally be high enough to cover the costs of new entrants and facilitate a

[31] *See NorthWestern,* 121 FERC ¶ 61,204 at P 6 (2007).

[32] *See, e.g.*, AEP August 9, 2010 Comments at 15 and EEI August 9, 2010 Comments at 9.

[33] WSPP, 134 FERC ¶ 61,169 at P 26.

[34] A five percent margin might be justified on the basis of our delivered price test in market-based rate proceedings, which defines who is in the relevant market by looking at generators whose delivered costs of power are within five percent of the market price.

market for ancillary services? If not, how much of an adder would be needed to cover the costs of new entrants? If such a new resource margin is used, should the Commission limit its use to sales among non-affiliated companies? In addition, should a new resource margin be disallowed for sales between transmission providers? [35] If such a new resource margin is used, should the Commission limit its use to times when the purchasing transmission provider has to rely on the third party provider?

d. We also seek comment on whether the WSPP Agreement [36] is an adequate vehicle for implementing a cost-based rate cap for ancillary service rates. If such a cap were established, should provision of all ancillary services made under the WSPP Agreement that remain at or below such cost-justified rate caps be considered just and reasonable, with no further mitigation measures needed? We seek comment on the following issues with respect to setting a cost-cap in the WSPP Agreement: How would such a cost cap be determined? Should such a cap for ancillary services be subject to the same requirements as the ''up to'' cap for power and energy in the current WSPP Agreement? Alternatively, could an experimental cap be based on the average ancillary service cost of all OATT sellers participating in the WSPP Agreement? Would it be sufficient to base an experimental cap on the costs of a ''representative sample'' of OATT sellers participating in the WSPP Agreement? How would a ''representative sample'' be determined? Should the cap include a new resource margin as described above? If yes, how would an appropriate adder be determined? Should a market monitor be established to oversee provision of ancillary service under the WSPP Agreement? Should this proposal be structured as a temporary pilot program, as were the original WSPP service schedules for market-based sales of energy and capacity?

e. Competitive solicitations can be one way of assuring just and reasonable rates. If transmission providers undertook open and transparent competitive solicitations would this help to facilitate the provision of ancillary services and ensure just and reasonable rates? Could a standardized competitive solicitation process be developed for particular regions or markets?

f. Finally, we seek comments on any other potential methods of mitigation, which would ensure that third-party provision of ancillary services at market-based rates remain just and reasonable, while facilitating the development of a competitive market.

4. Advancing the Goals of the Frequency Regulation NOPR in all Regions

22. In the Frequency Regulation NOPR, we proposed to require all ISOs and RTOs to compensate resources that provide frequency regulation in a manner that reflects the resource's performance in order to remedy undue discrimination.[37] In comments in that proceeding, NaturEner questioned whether the NOPR proposal can be extended to the areas outside of RTOs and ISOs.[38] As the Frequency Regulation NOPR notes, outside of RTOs and ISOs, transmission providers typically procure frequency regulation resources as part of their overall mix of resources, and seek cost recovery for those resources through a cost-based rate.[39] Assuming a third-party purchase is allowed and pass-through has been permitted as discussed earlier, we seek comment on whether transmission providers could compensate the frequency regulation resources they procure based on the principles proposed in the Frequency Regulation NOPR, and seek to include such costs in their Schedule 3 rates. Accordingly, we seek comment on whether the goals of the Frequency Regulation NOPR can be extended to regions outside the organized wholesale energy markets. Because these regions largely lack competitive markets for ancillary services, the Commission seeks comments on different potential frameworks under which the speed and accuracy of frequency regulation resources might be appropriately valued.

a. Were we to allow a cost-based cap for frequency regulation service in the WSPP Agreement as described above, how could that cap reflect an individual resource's performance?

b. Should we allow transmission customers that self-supply frequency regulation service to determine the amount of capacity they procure based on the third-party resource's performance capability? For instance, if a transmission customer is required to purchase 2 MW of frequency regulation service under *pro forma* OATT Schedule 3, should we allow that customer to purchase less capacity if it purchases from a resource that responds more quickly and accurately than the resources the transmission provider uses to provide service under Schedule 3? If so, how should we determine the amount of capacity the transmission customer is required to purchase?

c. Is there any other way to extend the goals of the Frequency Regulation NOPR outside of the ISOs and RTOs?

B. Accounting and Reporting Requirements for Energy Storage Resources

23. The Commission's accounting [40] and financial reporting requirements [41] for public utilities [42] are designed to provide information about a reporting entity's financial condition and results of operation. This information is important in developing and monitoring rates, making policy decisions, and informing the Commission and the public about the activities of entities that are subject to these accounting and reporting requirements.[43]

24. Under the Commission's accounting and reporting requirements, public utilities must record and classify electric plant assets in the prescribed primary plant accounts based on the purpose served or use of the asset to

[35] For purposes of this question, our use of the term transmission provider includes sales by its wholesale merchant function.

[36] The WSPP Agreement was initially accepted by the Commission on a non-experimental basis in 1991, and provided for flexible pricing for coordination sales and transmission services. *See Western Sys. Power Pool, 55 FERC ¶ 61,099, order on reh'g,* 55 FERC ¶ 61,495 (1991) *aff'd in relevant part and remanded in part sub nom. Environmental Action and Consumer Federation of America* v. *FERC, 996 F.2d 401, 302 U.S. App. D.C. 135 (DC Cir. 1992), order on remand,* 66 FERC ¶ 61,201 (1994). The WSPP Agreement as it exists today permits sellers of electric energy to charge either an uncapped market-based rate (for public utility sellers, they must have obtained separate market-based rate authorization from the Commission to do this), or an ''up to'' cost-based ceiling rate. For sellers without market-based rate authority, the cost-based rate under the WSPP Agreement consists of an individual seller's forecasted incremental cost plus an ''up to'' demand charge based on the average fixed costs of a subset of the original parties to the WSPP Agreement, so long as the seller can justify the use of this charge based on its own fixed costs. Otherwise, the seller must file a separate stand-alone rate schedule that is cost-justified based on the individual seller's own costs. Currently, there are over 300 parties to the WSPP Agreement located throughout the United States and Canada, including private, public and governmental entities, financial institutions and aggregators, and wholesale and retail customers.

[37] *Frequency Regulation Compensation in the Organized Wholesale Power Markets,* FERC Stats. & Regs. ¶ 36,672 (2011) (Frequency Regulation NOPR).

[38] *See* NaturEner, Comments, Docket No. RM11–7–000, at 3–4 (filed May 2, 2011).

[39] *See* Frequency Regulation NOPR, 134 FERC ¶ 61,124 at n.8.

[40] 18 CFR part 101.

[41] 18 CFR part 141.

[42] The term ''Public Utility'' means any person who owns or operates facilities subject to the jurisdiction of the Commission under the Federal Power Act. 18 CFR part 101 (Definition No. 29).

[43] Applicants for market-based rate authority that do not sell under cost-based rates frequently seek and typically are granted waiver of many or all of these requirements.

produce, transmit, or distribute electric energy. In addition, public utilities must also record and classify operation and maintenance (O&M) expenses related to such plant assets based on the specific activity the efforts support. The electric plant assets and related O&M expenses must be reported in annual and quarterly FERC Form Nos. 1, 1–F, and 3–Q reports [44] that are maintained in accordance with the Uniform System of Accounts (USofA).[45]

25. The roles of conventional production, transmission, and distribution resources are well understood and each has established method(s) of accounting, reporting, and cost-based rate recovery. However, the same is not necessarily true of new energy storage resources,[46] which can operate in ways that resemble production, transmission and/or distribution.[47] Energy storage resources are generally capable of providing multiple services with various benefits to the grid. Moreover, while committing not to provide other services is one method of addressing the Commission's concerns with cross-subsidization and inappropriate competitive impacts when a storage device seeks transmission rate recovery, the Commission remains open to alternative proposals to address those concerns. Accordingly, public utilities using energy storage resources might seek multiple methods of cost recovery for their investments in, and use of, the assets to provide various utility services. Consequently, due to the potential to use certain storage technologies to provide multiple services and the possibility that a public utility could simultaneously recover costs under both cost-based and market-based rates, the Commission seeks comment on whether current accounting and reporting requirements for activities and costs relating to the operations of new electric energy storage resources provide sufficient transparency.

26. In addition, there are questions concerning the concept of using a storage device to provide a transmission service and using a storage device to ''substitute'' for, or defer, a certain amount of transmission service. Transmission service is the movement of electric energy over distance. To the extent that storage devices like capacitor banks and batteries are used, for example, to provide reactive support to help move electric energy over distance, the Commission has found that the cost can be considered part of the cost of providing transmission service in those circumstances. The storage device in this scenario is ''used and useful'' to the provision of transmission service, and thus its costs may be included in the rates that transmission customers pay. By contrast, the use of storage for transmission deferral or substitution is arguably different from the provision of transmission service subject to our rate jurisdiction. This is because, rather than supporting the movement of electric energy over distance, this concept posits the use of storage or other assets to provide electric energy at a given point on the system as a replacement for a certain amount of transmission service from elsewhere to that point on the system. The Commission seeks comment on this distinction.

27. In the Storage RFC, Staff invited comments on, among other things, accounting and reporting modifications to the Commission's accounting and financial reporting requirements, which might facilitate the development and monitoring of rates related to new electric energy storage resources for cost-of-service rate purposes.

28. Numerous comments were received regarding the need for updating the USofA and FERC annual reports. Some commenters were supportive of revising the Commission's current accounting and reporting requirements to accommodate new electric energy storage resources; [48] other commenters indicated that revisions are unnecessary as the current requirements sufficiently accommodate energy storage.[49] However, most comments received were general in nature. Therefore, the Commission seeks specific details regarding whether and, if so how, to amend the current accounting and reporting requirements to specifically account for and report energy storage operations and activities.

Proposed Accounting and Reporting for Comment

29. The Commission's existing accounting requirements stipulate that utility plant costs be classified and accounted for in the following functional classifications: Steam Production, Nuclear Production, Hydraulic Production, Other Production, Transmission, Distribution, Regional Transmission and Market Operation, and General.[50] These plant classifications have associated primary plant accounts as well as O&M expense accounts. However, none of the primary plant or O&M expense accounts specifically provides for the accounting of costs related to new energy storage resources and operations.

30. As such, it may be difficult for owners of these technologies to complete their reporting requirements. This in turn would make it difficult for regulators to determine costs and establish appropriate rates for new energy storage technologies. Therefore, the Commission is seeking comments on accounting for the costs of energy storage resources and associated O&M expenses.

31. In addition, as detailed below, some public utilities will need to purchase or internally generate power for use in storage operations. However, the USofA does not have specific accounts for recording the cost of power purchased or generating expenses incurred in storage operations. Therefore, we seek comments on the appropriate accounting for these items.

32. Public utilities that receive rate approval to recover cost under more than one cost recovery method can potentially earn multiple revenue streams from the provision of multiple services using a single storage unit or system. This can lead to revenues earned pursuant to services provided under a cost-based rate subsidizing the cost of a different service that is provided under a market-based rate or vice-versa. If this occurs, the Commission's rule against cross-subsidization would be violated and its ability to appropriately develop and monitor cost-based rates of energy storage operations would be impacted.

[44] FERC Form No. 1, Annual Report for Major Electric Utilities, Licensees and Others (Form No. 1), 18 CFR 141.1; FERC Form No. 1–F, Annual Report for Nonmajor Public Utilities and Licensees (Form No. 1–F), 18 CFR 141.2; and FERC Form No. 3–Q, Quarterly Financial Report of Electric Utilities, Licensees, and Natural Gas Companies (Form No. 3–Q), 18 CFR 141.400.

[45] 18 CFR part 101.

[46] Pumped storage hydroelectric facilities are also energy storage resources. However, like other conventional production assets, the Commission has established methods of accounting, reporting and rate recovery associated with operation of pumped storage resources. Thus, we do not seek comment on whether the current accounting and reporting requirements for pumped storage hydroelectric assets or operations should be revised.

[47] For example, like a generator, an energy storage resource may be able to act as a power marketer, arbitraging differences in peak and off-peak energy prices or selling ancillary services; and similar to a transmission asset (*e.g.*, a capacitor) an energy storage resource could provide voltage support on the grid, or serve other purposes that support transmission service.

[48] *See, e.g.*, AEP August 9, 2010 Comments at 7; ITC Companies August 9, 2010 Comments at 14; and M-S-R Public Power Agency and the City of Santa Clara, California August 9, 2010 Comments at 13.

[49] *See, e.g.*, NRECA August 6, 2010 Comments at 13; AES Energy Storage, LLC August 9, 2010 Comments at 8; and FirstEnergy August 9, 2010 Comments at 6.

[50] In the Form Nos. 1 and 1–F, the Steam, Nuclear, Hydraulic, and Other plant functions are grouped as ''Production Plant'' functions.

Therefore the Commission seeks comments on accounting for revenues of energy storage operations.

33. Lastly, to address our transparency concerns for Form Nos. 1 and 1–F as they relate to reporting requirements associated with energy storage assets and operations, we seek comments on changes to the forms that may be needed to enhance their usefulness regarding the development and monitoring of cost-based rates.

1. New and Modified Plant Accounts

34. As we have indicated, the costs of new energy storage technologies are not explicitly provided for in the existing primary plant accounts. The Commission seeks comment on how to provide for financial transparency of these costs, as well as how to address issues that may develop in accounting and reporting for storage assets due to the potential to use the assets to provide multiple services.

35. We believe there may be a number of options to address these issues. For example, new plant accounts could be added to the production and transmission functions and an existing plant account could be revised in the distribution function. The account that could be revised in the distribution function is Account 363, Storage Battery Equipment.

36. The current instructions of Account 363 provide for the inclusion of the cost of storage battery equipment used for the purpose of supplying electricity to meet emergency or peak demands. The instructions to Account 363 could be revised to expand the items includible in the account to recognize the unique operating characteristics of new energy storage technologies which may provide services other than supplying electricity to meet emergency or peak demands.[51]

37. We seek comment on these ideas and any alternatives that commenters may propose. Specifically:

a. Should new accounts for energy storage plant and equipment be created and an existing account be revised as discussed in the above example, should new accounts be created and no existing accounts used, or do the existing primary plant accounts sufficiently provide for energy storage plant and equipment? Please elaborate. Also, if applicable, provide examples of new accounts and existing accounts, including account instructions that could be created or revised to account for energy storage resources.

b. If the Commission were to continue use of existing primary plant accounts for energy storage resources, which accounts will provide the transparency needed to develop and monitor cost-based rates? Would revisions to the instructions of the accounts be required to account for energy storage resources? If so, please provide insight into what may be required.

c. Should the cost of new energy storage plant and equipment be recorded within existing utility plant functional classifications (*i.e.*, transmission, distribution, and production) or should a new functional classification be created for energy storage? What are the benefits of one approach over the other? If the Commission were to create a new classification(s), please comment on the specific plant accounts and account instructions that would be created or modified for inclusion in the new asset class.

d. Are there any other accounting issues that relate to accounting for energy storage plant and equipment that should be considered? If so, provide options to address the issues.

2. Cost of Power Used in Storage Operations

38. Some public utilities operating storage resources may purchase electricity and store it to arbitrage the difference between the sales price of on-peak and off-peak electricity. In these instances, public utilities will typically purchase and store low cost off-peak electricity that they will sell at higher prices during on-peak periods. The USofA requires that purchases of power for resale be recorded at cost in Account 555, Purchased Power. Thus, this account may sufficiently provide for the recording of the cost of electricity stored in storage operations that is sold in wholesale electricity markets.

39. Additionally, Account 555 also provides for the recording of net settlements for the exchange of electricity or power. Exchange transactions may involve exchanges such as off-peak energy for on-peak energy or transactions under pooling or interconnection agreements wherein there is a balancing of debits and credits for energy or capacity. The net settlement amount is generally the difference between the cost of power received and the cost of power returned at the respective transaction periods over an agreed upon timeframe.

40. Public utilities engaging in such exchange transactions could be required to record the net settlement amount in Account 555 consistent with the instructions of the account. Also, consistent with these instructions, distinct purchases and sales that are not exchange transactions would be recorded as separate purchases and sales. In this case, purchases made for resale purposes could be recorded in this account; however, if the purchase is not made for resale purposes then the transaction may need to be reported in a different account.

41. Electricity used in storage operations will not be purchased for resale or through exchange transactions in all instances. For example, electricity may be purchased and stored for later use in the provision of transmission services or for other jurisdictional or non-jurisdictional purposes. Moreover, some RTO tariffs may permit the energy that storage facilities absorb and return as part of their provision of frequency regulation services to be netted such that no purchase of energy for resale occurs; only the energy lost in conversion is purchased as part of station power load, and that purchased power is not resold. Since Account 555 does not specifically provide for recording the cost of power purchased and consumed while providing this and similar types of energy consuming services the account may not be the appropriate account to record the power purchases.

42. In some cases, depending on the operating characteristics of a storage resource or the utility services it provides, a public utility may be required to sustain a particular state of charge on its storage device to provide utility service. For example, if a storage device is primarily intended to provide reserves, then it needs to maintain an appropriate state of charge to allow it to discharge the reserved power when needed. In contrast, if a storage device is primarily intended to provide frequency regulation, which it will do through nearly continuous and off-setting charge/discharge operations, then it may not need to achieve any one particular beginning state of charge in order to provide the targeted utility service.

43. With respect to energy storage devices that must sustain a particular state of charge to provide a particular service, the conversion and storage process charges the device so that it reaches the state of charge or capacity necessary for doing work. To initially attain and to sustain a particular state of charge where needed, public utilities may internally generate electricity, purchase it in retail or wholesale markets, or engage in exchange

[51] For example, as a distribution resource recorded in the account the asset could assist with frequency or voltage regulation which, at times, may require it to withdraw electricity from the grid rather than supply it and for purposes other than to meet emergency or peak demands.

transactions with merchant generators or centrally dispatched power pools.

44. The cost of power purchased to initially attain a specific state of charge at the first installation of the storage assets, prior to the commencement of utility service, could be considered a base charge and accounted for as such by being included in the total cost of the asset. Further, public utilities that must purchase or internally generate power to sustain a working state of charge could possibly account for the cost of purchased power or generation by recording it in existing accounts such as Account 555, Purchased Power, Account 501, Fuel, or other existing O&M expense accounts, as appropriate. The Commission seeks comment on these ideas, as well as alternatives. Specifically:

a. Should power purchased and stored for resale be recorded in Account 555? Would revisions to the instructions of the account be required to account for the power purchases; if so, please provide insight into what may be required. Are there any alternative methods to account for these costs?

b. Should power purchased that will not be sold for resale but will instead be consumed during the provision of services such as frequency regulation be accounted for in Account 555, or a different existing O&M expense account? Please elaborate. Also, should new accounts be created or, alternatively, should existing accounts be revised? We welcome examples of new or existing accounts and instructions that could be created or revised, respectively, to account for power purchased for use in storage operations.

c. We also seek comment on whether power purchased to initially attain a state of charge should be accounted for as a base charge and included as a component cost of energy storage plant and equipment. Are there any alternative methods to account for power purchased to initially attain a state of charge?

d. Should power purchased to sustain a particular state of charge be recorded as an expense in Account 555, a different existing O&M expense account, or should a new expense account be created? Please explain in detail and, if applicable, provide examples of existing and new accounts that could be used and related account instructions.

e. How should the cost of fuel, or other direct costs, incurred to internally generate power for use in energy storage operations be accounted? What expense accounts should be used to account for the costs?

f. Are there any other accounting issues that should be considered that relate to accounting for power purchased or exchanged, and fuel and other direct generating costs incurred for energy storage operations? If so, provide options to address the issues.

3. Revenues From Providing Energy Storage Services

45. The USofA currently requires public utilities to record revenues derived from electric operations in specific revenue accounts based on the relevant revenue generating activity. Revenues derived from energy storage operations may involve the same revenue generating activities embodied in the existing revenue accounts. For example, Account 447, Sales for Resale, provides for the recording of revenues from electricity supplied to other electric utilities or public authorities for resale purposes. Electricity from storage operations can be sold for resale in wholesale markets, which would require the resulting revenues to be recorded in Account 447, Sales for Resale. Thus, in this and similar instances, it is possible that the existing revenue accounts could be used to account for revenues derived from the operations of storage assets.

46. However, because a public utility storage operator can potentially recover costs of operating a storage unit under both cost- and market-based rate constructs, recording revenues from storage operations in existing revenue accounts may not provide sufficient transparency of revenues derived from storage operations. As we explained above, where a storage device seeks transmission cost-of-service rates, any revenues from other services it provides may raise cross-subsidization issues. Thus, adequate transparency is needed to allow the Commission and others to monitor for cross-subsidization in this regard.

47. The Commission seeks comment on how to address this issue as it relates to the development and monitoring of cost-based rates. Specifically:

a. Are existing revenue accounts sufficient to capture potential revenues associated with storage operations or should new accounts be created? If the existing accounts are used, would the instructions to the accounts need to be revised? We welcome examples of revisions to the account instructions, if any, that may be needed to account for revenues from storage operations. Also, if applicable, provide examples of new revenue accounts and instructions that could be created.

b. Would recording revenues from storage operations in one account, for example Account 456, Other Electric Revenues, sufficiently address revenue transparency issues? How would this accounting impact transparency as it relates to the development and monitoring of cost-based rates? If the Commission were to require revenues derived from storage operations to be accounted for in one account, what account should be used, why should it be used, and would the instructions of the account need to be revised?

c. Should new revenue accounts be created to record revenues from storage operations? Are there examples of accounts and account instructions that could be created to record the revenues?

d. Are there any other accounting issues that should be considered that relate to accounting for revenues derived from storage operations? If so, provide options to address the issues.

4. Operation and Maintenance Expenses

48. Different energy storage technologies have different operating cost structures. For example, flywheels generally have relatively low O&M expenses but higher upfront capital costs compared to batteries, which tend to have lower upfront capital costs, but higher O&M expenses. These assets also have differing service lives as compared to each other and as compared individually to conventional utility assets. Furthermore, the service life of a storage asset may be impacted by the demands of the particular function or functions that the asset serves. For example, a battery storage device used exclusively for frequency regulation may have a different service life from one used to shift off-peak generation to on-peak periods.

49. The service life of an asset will typically correlate to the rate(s) at which it is depreciated for accounting and rate making purposes. It is important to properly capture expenses from the use of the assets for cost-of-service rate purposes. The USofA does not provide specific accounts to record O&M expenses of energy storage operations. Therefore, we seek comments on the accounting requirements for O&M expenses.

a. Are existing O&M expense accounts sufficient to capture costs associated with storage operations? Are there any revisions to existing accounts or account instructions that would be required to account for O&M expenses of storage operations?

b. Should new O&M expense accounts be created? If so, provide examples of new accounts and account instructions that could be created to account for O&M expenses of storage operations.

c. What accounting issues may arise due to the use of a single storage resource to provide services simultaneously under cost- and market-based rate recovery constructs? Are there options on how these issues may be addressed?

d. What accounting issues may arise due to the joint ownership of a storage facility by separate independent companies that propose to use their respective ownership shares of the facility to each provide a different jurisdictional service (*e.g.*, wholesale sales of electricity and transmission voltage support) under cost- and market-based rate recovery mechanisms? Are there options on how these issues may be addressed?

e. Are there other accounting issues that should be considered that relate to accounting for O&M expenses associated with storage operations? If so, provide options to address the issues.

5. Form Nos. 1 and 1–F

50. To develop and monitor cost-based rates, the Commission needs access to financial data, such as capital and operating costs of relevant land, equipment, and labor, as well as nonfinancial data, such as volumes sold. For energy storage resources, cost data relating to their unique equipment and processes, which are separate from those for traditional production plants and transmission and distribution assets, are also required. The Form Nos. 1 and 1–F may need to be amended to accurately capture these financial and non-financial data. Therefore, the Commission seeks comment on whether the Form Nos. 1 and 1–F should be revised and, if they should, how to revise them to include information on energy storage plant and operations.

a. Should the Form Nos. 1 and 1–F be amended to provide the detailed information required to monitor energy storage operations and develop cost-of-service rates?

b. We welcome examples of new schedules that could be created or existing schedules that could be revised to report the costs of energy storage plant and equipment and O&M expenses. To provide for transparent reporting of costs included in the accounts, it may be helpful if such schedules included the following, among other possible items: (1) Primary plant accounts and amounts included and reported in the general utility plant accounts 101, 103, 106 and 107 for energy storage plant by function; and (2) expense accounts and amounts included and reported in the general O&M expense accounts 401 and 402 for storage operations by function.

c. We also welcome examples of new schedules that could be created or existing schedules that could be revised to report the financial and non-financial data of storage operations. To provide for transparent reporting of this data, it may be helpful if such schedules included the following types of financial and non-financial operational data, among other possible items: (1) Name and location of energy storage plant; (2) Megawatt hours (MWhs) of power purchased, generated, or received in exchange transactions for storage, MWhs of power delivered to the grid to support production, transmission, or distribution operations, MWhs of power lost during conversion, storage and discharge of energy by function, and MWhs of power sold for resale; (3) cost of power purchased for storage operations, fuel costs for storage operations associated with self-generated power, and other costs associated with self-generated power; and (4) revenues from energy storage operations by service provided and revenues from stored energy sold for resale.

d. Should the same financial and nonfinancial data of energy storage assets and operations required to be reported in Form Nos. 1 and 1–F also be reported to the Commission in the Form No. 3–Q? If not, what information on storage assets and operations should be included in the Form No. 3–Q?

III. Comment Procedures

51. The Commission invites interested persons to submit comments on the matters, issues and specific questions identified in this notice. Comments are due 60 days from publication in the **Federal Register**. Comments must refer to Docket No. RM11–24–000, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

52. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov*. The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

53. Commenters unable to file comments electronically must mail or hand deliver an original and copy of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

54. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

IV. Document Availability

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

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

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

By direction of the Commission.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

Appendix

List of Commenters in Docket No. AD10–13–000

A123 Systems, Inc.
AES Energy Storage, LLC (AES Energy Storage)
American Electric Power Service Corporation (AEP)
American Public Power Association
Applied Intellectual Capital
Arizona Public Service Company
Beacon Power Corporation
Brookfield Renewable Power Inc. (Brookfield)
California Department of Water Resources State Water Project
California Energy Storage Alliance
California Independent System Operator Corporation
California Public Utilities Commission
Christensen Associates Energy Consulting
City of Santa Clara, California and the M-S-R Public Power Agency
The Coalition to Advance Renewable Energy through Bulk Storage (CAREBS)

Demand Energy
Duke Energy Corporation
Edison Electric Institute (EEI)
Electric Power Supply Association
Electricity Consumers Resource Council
Electricity Storage Association
Energy Cache
Exelon Corporation (Exelon)
FirstEnergy Service Company (FirstEnergy)
General Compression
Grasslands Renewable Energy LLC
ITC Companies
MegaWatt Storage Farms, Inc.
MidAmerican Energy Holdings Company
Modesto Irrigation District
National Alliance for Advanced Technology Batteries (NAATBatt)
National Electrical Manufacturers Association
National Grid USA
National Hydropower Association
National Rural Electric Cooperative Association (NRECA)
New York Transmission Owners
NGK Insulators, Ltd (NGK/TI)
NSTAR Electric Company
Ohio Consumers'' Counsel
Pacific Gas and Electric Company
PJM Interconnection, L.L.C.
Powerex Corp.
Premium Power Corporation
Primus Power Corporation
PSEG Companies
Public Interest Organizations
Puget Sound Energy, Inc.
Riverbank Power Corp.
San Diego Gas & Electric Company (SDG&E)
Six Cities CA
Rodney G. Smith
Southern California Edison Company (SCE)
Southern Company Services, Inc.
Southwest Power Pool, Inc.
Starwood Energy Group Global, LLC.
SunEdison
Symbiotics, LLC
Transmission Agency of Northern California
Viridity Energy, Inc.
Western Grid Development LLC
Xtreme Power Inc. (Xtreme Power)

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Parts 627

[FHWA Docket No. FHWA–2011–0046]

RIN 2125–AF40

Value Engineering

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: This notice proposes updated regulations to enhance the integration of value engineering (VE) analysis in the planning and development of highway improvement projects. The intent of these actions is to bring the FHWA's VE regulations up-to-date and consistent with prior changes in legislation and regulations.

DATES: Comments must be received on or before August 22, 2011. Late comments will be considered to the extent practicable.

ADDRESSES: Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, or submit electronically at *http://www.regulations.gov* or fax comments to (202) 493–2251. All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., E.T., Monday through Friday, except Federal holidays. Those desiring notification or receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, Page 19477–78), or you may visit *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Jon Obenberger, Preconstruction Team Leader, Office of Program Administration, (202) 366–2221, or Mr. Michael Harkins, Office of the Chief Counsel, (202) 366–4928, Federal Highway Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Office hours are from 8 a.m. to 4:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

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

An electronic copy of this document may also be downloaded from the Office of the **Federal Register's** home page at: *http://www.gpoaccess.gov.*

Background

This rulemaking proposes to modify existing regulations to make it consistent with several changes in applicable laws and regulations. These revisions will ensure compatibility with 23 U.S.C. 106 and the Office of Management and Budget (OMB) Circular A–131 on Value Engineering. These revisions will also address certain findings contained in a 2007 Office of Inspector General (OIG) report on value engineering in the Federal-Aid Highway Program (FAHP) *http://www.oig.dot.gov/sites/dot/files/pdfdocs/mh2007040.pdf*) in which the OIG recommended that the FHWA make certain changes to the VE policy. This rulemaking would not change the reporting structure now in place, revise the threshold of projects for which a value engineering analysis is required, or otherwise impose any new burdens on States.

The regulation is also being revised to enhance the consistency with the VE analyses that are conducted and to enhance FHWA's stewardship and oversight of these regulations. These revisions will advance the integration of VE analysis into the planning and development of Federal-aid projects. These revisions will facilitate enhancements to the VE analyses agencies conduct and will foster the use of innovative technologies and methods while eliminating unnecessary and costly design elements, thereby improving the projects' performance, value, and quality, and reducing the time to develop and deliver projects. The proposed revisions are discussed in the section analysis below.

The VE analyses on Federal-Aid highway projects was first established by Congress in the Federal-Aid Highway Act of 1970. The OMB Circular A–131 on Value Engineering which was issued in May 1993 (*http://www.whitehouse/gov/omb/circulars_a131*) requires all Federal agencies to establish and maintain a VE program to improve the quality of their programs and acquisition functions. To advance these VE programs, Federal agencies are required to develop and maintain policies and procedures to ensure a VE analysis is conducted on appropriate projects and report annually on the results and accomplishments of the analyses conducted and the program's accomplishments.

In late 1995, Congress passed the National Highway System Designation Act which directed the Secretary to establish a program that required States to carry out a VE analysis for all Federal-aid highway projects on the National Highway System with an estimated total cost of $25 million or more. On February 14, 1997, the FHWA published its VE regulations in 23 CFR 627 formally establishing the FHWA VE program along with the requirement that State Transportation Agencies (STAs) create and sustain a VE program.

Section 1904 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), required that a VE analysis be conducted for bridge projects with an estimated total cost of $20 million or more and any other projects designated by the Secretary of Transportation.

The FHWA annually collects and reports on VE accomplishments achieved within the Federal-aid and Federal Lands Highway Programs. For VE studies conducted during the planning and development phases of projects, the FHWA tracks the number of studies conducted; the number of proposed and implemented recommendations; the value of the implemented recommendations; information regarding the STA's VE program (*e.g.,* policies, procedures, training conducted); and FHWA's stewardship and oversight of the VE program. Conducting VE analyses continues to be an effective tool in improving the quality and cost effectiveness of the FAHP projects. In FY 2009 STAs performed VE analyses on 426 Federal-aid highway projects and approved and implemented a total of 1,444 VE recommendations, resulting in a construction cost savings of $1.693 billion. In addition, a savings of $44.83 million was realized as the result of approved construction VE change proposals (VECP) that were submitted by contractors and accepted by STAs. Additional information on STA, local authority, and FHWA VE programs and practices is available at: *http://www.fhwa.dot.gov/ve.*

Section-by-Section Discussion of the Proposals

The FHWA is proposing to revise the regulation at 23 CFR part 627—Value Engineering as follows:

Section 627.1—Purpose and Applicability

Section 627.1 would be amended to clarify the relationship between a VE program, the need to establish VE policies and procedures, when a VE analysis is required on applicable projects, and the need to incorporate the approved recommendations into the project's plans. These amendments would also clarify the need for VE programs to establish the policies, procedures, and functions to monitor, assess, and report on the VE program, VE analyses conducted, and VECPs accepted.

Section 627.3—Definitions

Section 627.3 would be amended to clarify and consistently reference the requirements associated with conducting a VE analysis versus a VE study. A definition will also be added to describe what a VE job plan is and how it may be used to document the VE analysis process and results of the activities that were conducted. A definition will be added to describe what a VECP is and how it may be used as a clause in a construction project's specifications and contract.

Section 627.5—Applicable Projects

The title of sec. 627.5 would be changed from General Principles and Procedures to Applicable Projects to clarify when a VE analysis is required by FHWA. Section 627.5(b) would be amended to clarify when a VE analysis shall be conducted on projects that utilize FAHP funding so that it is consistent with the statutory changes contained in sec. 1904 of SAFETEA–LU. Section 627.5(c) and (d) would clarify the requirements associated with conducting the VE analysis and then splitting the project into multiple construction contracts in final design.

Section 627.7—VE Programs

A new section, sec. 627.7, would clarify the responsibilities and expectations associated with the existing requirement that STAs develop and sustain a VE program, and identify a VE program coordinator responsible for leading this program. Section 627.7(b) would clarify the responsibilities of STAs and local authorities to ensure that the required VE analysis is conducted on all of the required projects within their State.

Section 627.9—Conducting a VE Analysis

A new section, sec. 627.9, would clarify the responsibilities associated with conducting a VE analysis. These revisions would clarify the required analysis to be conducted, when the analysis should be conducted, identifying and selecting recommendations, implementing the approved recommendations, evaluating or validating the influence of the implemented recommendations, and encouraging the use of VECPs in the construction phase of projects.

Rulemaking Analyses and Notices

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

The FHWA has determined that this proposed rule would not be a significant regulatory action within the meaning of Executive Order 12866 and would not be significant within the meaning of the U.S. Department of Transportation regulatory policies and procedures.

The proposed amendments revise requirements for conducting VE analyses. It is anticipated that the economic impact of this rulemaking would be minimal; therefore, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (RFA) (Pub. L. 96–354, 5 U.S.C. 60l–612), the FHWA has evaluated the effects of this proposed rule on small entities and anticipates that this action would not have a significant economic impact on a substantial number of small entities. The proposed amendment addresses VE studies performed by STAs on certain projects using Federal-aid highway funds. As such, it affects only States, and States are not included in the definition of small entity set forth in 5 U.S.C. 601. Therefore, the RFA does not apply, and the FHWA certifies that the proposed action would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This NPRM would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995, 109 Stat. 48). The actions proposed in this NPRM would not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $140.8 million or more in any one year (2 U.S.C. 1532). Further, in compliance with the Unfunded Mandates Reform Act of 1995, FHWA will evaluate any regulatory action that might be proposed in subsequent stages of the proceeding to assess the affects on State, local, and Tribal governments and the private sector. Additionally, the definition of ''Federal Mandate'' in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or Tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal-aid highway program permits this type of flexibility.

Executive Order 13132 (Federalism Assessment)

This proposed action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, dated August 4, 1999, and it has been determined that this proposed action does not have a substantial direct effect or sufficient federalism implications on States that would limit the policymaking discretion of the States. Nothing in this proposed

rule directly preempts any State law or regulation or affects the States' ability to discharge traditional State governmental functions.

Executive Order 12372 (Intergovernmental Review)

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

Paperwork Reduction Act

FHWA invites public comment about our intention to request the OMB approval for a new information collection, which is summarized in Background section of this document. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*).

Collection Title: Value Engineering Analyses on Federal-aid Highway Projects.

Type of Request: New information collection requirement.

Respondents: 50 States, the District of Columbia, and Puerto Rico.

Frequency: One collection every year.

Estimated Average Burden per Response: It will take approximately 30 minutes to compile the results of each VE analysis that is conducted. It will also take approximately 3 hours to compile the results of all of the VE analyses that are conducted annually in each State DOT, the District of Columbia, and Puerto Rico and to submit these results to FHWA. Nationwide on average there are approximately 400 VE analyses that are conducted annually.

Estimated Total Annual Burden Hours: Approximately 356 hours per year.

When submitting comments for this proposed information collection, use the FHWA Docket ID Number FHWA–2011–0046. You may use by any of the following methods:

Web Site: For access to the document to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Document Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

National Environmental Policy Act

The FHWA has analyzed this proposed action for the purpose of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and anticipates that this action would not have any effect on the quality of the human and natural environment, because this rule would merely establish the requirements that apply to VE analyses whenever an applicable Federal-aid highway project is to be constructed.

Executive Order 13175 (Tribal Consultation)

The FHWA has analyzed this proposed action under Executive Order 13175, dated November 6, 2000, and believes that this proposed action would not have substantial direct effects on one or more Indian Tribes; would not impose substantial direct compliance costs on Indian Tribal governments; and would not preempt Tribal law. This proposed rulemaking merely establish the requirements that apply to VE analyses whenever an applicable Federal-aid highway project is to be constructed and would not impose any direct compliance requirements on Indian Tribal governments, nor would it have any economic or other impacts on the viability of Indian Tribes. Therefore, a Tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

The FHWA has analyzed this proposed action under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution or Use. We have determined that this proposed action would not be a significant energy action under that order because any action contemplated would not be likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, the FHWA certifies that a Statement of Energy Effects under Executive Order 13211 is not required.

Executive Order 12630 (Taking of Private Property)

The FHWA has analyzed this proposed rule under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights. The FHWA does not anticipate that this proposed action would affect a taking of private property or otherwise have taking implications under Executive Order 12630.

Executive Order 12988 (Civil Justice Reform)

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

Executive Order 13045 (Protection of Children)

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

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 627

Grant programs-transportation, Highways and roads.

Issued on: June 13, 2011.

Victor M. Mendez,

Administrator.

In consideration of the foregoing, the FHWA proposes to revise 23 CFR part 627 as follows:

PART 627—VALUE ENGINEERING

Sec.
627.1 Purpose and Applicability.
627.3 Definitions.
627.5 Applicable Projects.
627.7 VE Programs.
627.9 Conducting a VE Analysis.

Authority: 23 U.S.C. 106(e), 106(g), 106(h), 112(a) and (b), 302, 315; and 49 CFR part 18.

§ 627.1 Purpose and Applicability.

(a) The purpose of this subpart is to prescribe the programs, policies and procedures for the integration of value engineering (VE) into the planning and development of all applicable Federal-aid highway projects.

(b) Each State transportation agency (STA) shall establish and sustain a VE program. This program must establish the policies and procedures identifying when a VE analysis is required on all applicable projects. These policies and procedures should also identify when a VE analysis is encouraged on all other

projects where there is a high potential to realize the benefits of a VE analysis.

(c) STAs and local authorities shall establish the policies, procedures, functions, and capacity to monitor, assess, and report on the performance of the VE program, along with the VE analyses that are conducted and Value Engineering Change Proposals (VECP) that are accepted.

§ 627.3 Definitions.

(a) *Project.* A portion of a highway that a STA or public authority proposes to construct, reconstruct, or improve as described in the preliminary design report or applicable environmental document. A project may consist of several contracts, or phases of a project or contract, which are implemented over several years.

(b) *VE analysis.* The systematic process of reviewing and assessing a project by a multidisciplinary team not directly involved in the planning and development phases of a specific project that is conducted to provide recommendations for:

(1) Providing the needed functions, including any community and environmental commitments, safely, reliably, efficiently, and at the lowest overall life-cycle cost (as defined in 23 U.S.C. 106(f)(2));

(2) Improving the value and quality of the project; and

(3) Reducing the time to develop and deliver the project.

(c) *VE Job Plan.* A systematic and structured plan of action for conducting and documenting a VE analysis and ensuring the implementation of the recommendations. The job plan must consist of and document:

(1) Gathering of information;

(2) Analyzing functions, worth, cost, performance, and quality;

(3) Speculating using creative techniques to identify alternatives that can provide the required functions;

(4) Evaluating the lowest life-cycle cost alternatives;

(5) Developing alternatives into fully supported recommendations;

(6) Documenting VE recommendations for review, approval, and implementation;

(7) Implementing recommendations; and

(8) Evaluating the implemented recommendations.

(d) *Value Engineering Change Proposal (VECP).* A construction contract provision by which the contractor proposes changes in the project's plans, designs, specifications, or contract documents. These proposed changes may improve the project's performance, value and/or quality, lower construction costs, or shorten the delivery time, while having no adverse impact on the project's overall life-cycle cost.

§ 627.5 Applicable Projects.

(a) STA's and local authorities shall conduct a VE analysis on each applicable project that utilizes Federal-aid highway funding and incorporate all approved recommendations into the project's plans, specifications and estimates.

(b) Applicable projects shall include the following:

(1) Each project located on the National Highway System (NHS) (as specified in 23 U.S.C. 103(a)) with an estimated total project cost of $25 million or more that utilizes Federal-aid highway funding;

(2) Each bridge project located on or off of the NHS with an estimated total project cost of $20 million or more that utilizes Federal-aid highway funding;

(3) Any Major Project (as defined in 23 U.S.C. 106(h)), both on or off of the NHS, that utilizes Federal-aid highway funding in any contract or phase comprising the Major Project;

(4) Any project identified in paragraphs (1), (2) or (3) of this subsection where:

(A) A three-year delay or longer occurs from when the final plans for a project are completed and the project advances to a letting for construction and the FHWA determines a substantial change has occurred to the project's scope or design; or

(B) A change is made to a project's scope or design after the final plans for the project were completed and it advances to a letting for construction, increasing the total project cost above the thresholds for conducting a VE analysis; or

(5) Any other Federal-aid project the FHWA determines to be appropriate.

(c) An additional VE analysis is not required if, after conducting the VE analysis required under this part for any project meeting the criteria of subsection (b), the project is subsequently split into smaller projects in the final design phase or if the project is programmed to be completed by the letting of multiple construction projects. However, the STAs may not avoid the requirement to conduct a VE analysis on an applicable project by splitting the project into smaller projects, or multiple construction projects, solely for the purpose of not conducting a VE analysis.

(d) FHWA may require more than one VE analysis to be conducted in the planning and development of Major Projects. The STA's VE program's policies and procedures shall identify when any additional VE analyses should be considered or conducted in the planning and development of Major Projects.

§ 627.7 VE programs.

(a) The STA must establish and sustain a VE program under which VE studies are conducted for all applicable projects.

(b) STA VE programs. The STA's VE program must:

(1) Establish and document VE program policies and procedures that ensure the required VE analysis is conducted on all applicable projects;

(2) Ensure the VE analysis is conducted prior to initiating the final design of a project and the approved recommendations to be implemented in the project are documented in a final VE report for each project;

(3) Monitor, assess, and disseminate an annual report to the FHWA consisting of a summary of all of the approved and implemented recommendations for all applicable projects requiring a VE analysis, the accepted VECPs, and VE program functions and activities;

(4) Establish and document policies, procedures, and contract provisions that identify if and when VECP's are allowed; the analysis, documentation, basis, and process for evaluating and accepting a VECP; and determine how the net savings of each VECP may be shared between the agency and contractor;

(5) Establish and document policies, procedures, and controls to ensure a VE analysis is conducted for applicable projects administered by local authorities and the results of these analyses are included in the VE program monitoring and reporting; and

(6) Provide for the review of any applicable project where a three-year delay or longer occurs from when the final plans are completed and the project advances to a letting for construction, to determine if a substantial change has occurred to the project's scope or design, which would require a VE analysis to be conducted.

(c) STAs and local authorities shall assure the required VE analysis has been performed on each applicable project and the approved recommendations are incorporated into the project's plans, specifications, and estimate.

(d) STA VE coordinators. STAs must designate a VE Program Coordinator to promote and advance VE program activities and functions. The VE Coordinator's responsibilities must include establishing and maintaining the STA's VE policies and procedures;

developing and sustaining a VE training and capacity building initiative; monitoring, assessing, and reporting on the VE analyses conducted and VE program; participating in periodic VE program and project reviews; submitting the required annual reports to the FHWA; and support the other elements of the VE program.

§ 627.9 Conducting a VE analysis.

(a) A VE analysis should be conducted as early as practicable in the planning or development of a project, preferably before the completion of the project's preliminary design. At a minimum, the VE analysis must be conducted prior to final design.

(b) The VE analysis should be closely coordinated with other project development activities. This assessment will improve the probability of proposed VE recommendations being accepted and incorporated into the project design without conflicting with or adversely impacting previous agency, community, or environmental commitments, the project's scope, and the development of construction schedules. The analysis to be conducted should include a consideration of combining or eliminating inefficient uses of the existing facility and explore the opportunity to refine the project's design or project plans to incorporate innovative technologies, materials, or methods to accomplish the project's purpose and design.

(c) Design-build projects meeting the applicability criteria specified in 23 CFR 627.1(b) must conduct a value analysis prior to the release of the Request for Proposals document.

(d) Projects requiring a VE analysis must:

(1) Use a multi-disciplinary team not directly involved in the planning or design of the project, with at least one individual who is trained and knowledgeable in VE analysis techniques and able to serve as the team's facilitator and coordinator;

(2) Develop and implement the VE Job Plan. The analytical methodology and tools to be used in support of the VE analysis that is conducted should follow recommended industry practices and FHWA guidance to evaluate the potential benefit and impacts that may be expected to occur with the proposed VE recommendations;

(3) Produce a formal written report outlining, at a minimum:

(i) Project information;

(ii) Identification of the VE analysis team;

(iii) Background and supporting documentation, such as information obtained from other analyses conducted on the project (*e.g.,* environmental, safety, traffic operations, constructability);

(iv) Documentation of the stages of the VE Job Plan which would include documentation of the life-cycle costs that were analyzed;

(v) Summarization of the analysis conducted;

(vi) Documentation of the proposed recommendations and approvals received at the time the report is finalized; and

(vii) The formal written report shall be retained for at least 3 years after the completion of the project (as specified in 49 CFR 18.42).

(e) For bridge projects, in addition to the requirements in subsection (d), the VE analyses must:

(1) Include bridge substructure and superstructure requirements that consider alternative construction materials; and

(2) Be conducted based on:

(A) An engineering and economic assessment, taking into consideration acceptable designs for bridges; and

(B) Using an analysis of life-cycle costs and duration of project construction.

(f) STAs and local authorities may employ qualified consultants (as defined in 23 CFR 172.3) to conduct a VE analysis. A consulting firm or individual must not be used to conduct or support a VE analysis if they have a direct or indirect conflict of interest in connection with the subject project.

(g) VECPs. STAs and local authorities are encouraged to use a VECP clause in an applicable project's specifications and contract, allowing the construction contractor to propose changes in the project's plans, specifications, or other contract documents. The STA and local authority will consider changes that could improve the project's performance, value and quality, shorten the delivery time, or lower construction costs, while having no adverse impact on the project's overall life-cycle cost. The basis for a STA or local authority to consider a VECP is the analysis and documentation supporting the proposed benefits that would result from implementing the proposed change in the project's contract or project plans.

(h) Proposals to accelerate construction after the award of the contract will not be considered a VECP and will not be eligible for Federal-aid highway program funding participation. Where it is necessary to accelerate construction, STAs and local authorities are encouraged to use the appropriate incentive or disincentive clauses so that all proposers will take this into account when preparing their bids or price proposals.

[FR Doc. 2011–15540 Filed 6–21–11; 8:45 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1904

[Docket No. OSHA–2010–0019]

RIN 1218–AC50

Occupational Injury and Illness Recording and Reporting Requirements—NAICS Update and Reporting Revisions

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Proposed rule.

SUMMARY: OSHA is proposing to update Appendix A to Subpart B of its Injury and Illness Recording and Reporting regulation. Appendix A contains a list of industries that are partially exempt from maintaining records of occupational injuries and illnesses, generally due to their relatively low rates of occupational injury and illness. The current list of industries is based on the Standard Industrial Classification (SIC) system. In 1997, the North American Industry Classification System (NAICS) was introduced to classify establishments by industry. The proposed rule would update Appendix A by replacing it with a list of industries based on NAICS and more recent injury and illness data.

The proposed rule would also require employers to report to OSHA, within eight hours, all work-related fatalities and all work-related in-patient hospitalizations; and within 24 hours, all work-related amputations. The current regulation requires an employer to report to OSHA, within eight hours, all work-related fatalities and in-patient hospitalizations of three or more employees.

DATES: *Written comments:* Comments must be submitted by September 20, 2011.

ADDRESSES: *Written comments:* You may submit comments, identified by docket number OSHA–2010–0019, or regulatory information number (RIN) 1218–AC50, by any of the following methods:

Electronically: You may submit comments electronically at *http://www.regulations.gov,* which is the Federal e-rulemaking portal. Follow the

instructions on the Web site for making electronic submissions;

Fax: If your submission, including attachments, does not exceed 10 pages, you may fax it to the OSHA docket office at (202) 693–1648; or

Mail, hand delivery, express mail, messenger, or courier service: You must submit three copies of your comments and attachments to the OSHA Docket Office, Docket Number OSHA–2010–0019, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2350 (OSHA's TTY number is (877) 889–5627). Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and docket office's normal business hours, 8:15 a.m.–4:45 p.m.

Instructions for submitting comments: All submissions must include the docket number (Docket No. OSHA–2010–0019) or the RIN (RIN 1218–AC50) for this rulemaking. Because of security-related procedures, submission by regular mail may result in significant delay. Please contact the OSHA docket office for information about security procedures for making submissions by hand delivery, express delivery, and messenger or courier service.

All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *http://www.regulations.gov.* Therefore, OSHA cautions you about submitting personal information such as social security numbers and birthdates.

Docket: To read or download submissions in response to this **Federal Register** notice, go to docket number OSHA–2010–0019, at *http://regulations.gov.* All submissions are listed in the *http://regulations.gov* index, however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through that Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA docket office.

Electronic copies of this **Federal Register** document are available at *http://www.regulations.gov.* This document, as well as news releases and other relevant information, is available at OSHA's Web site at *http://www.osha.gov.*

FOR FURTHER INFORMATION CONTACT: *For press inquiries:* OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202)–693–1999.

For general and technical information on the proposed rule: OSHA Office of Statistical Analysis, Room N–3641, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2400.

SUPPLEMENTARY INFORMATION: OSHA's current regulation at Section 1904.2 partially exempts certain lower-hazard industries classified in Standard Industrial Classification (SIC) codes 52 through 89 from injury and illness recordkeeping requirements. Lower hazard industries are those industries with an average Days Away, Restricted, or Transferred (DART) rate at or below 75 percent of the national average DART rate. The DART rate represents the total non-fatal injuries and illnesses resulting in days away from work, restricted work activity, and/or job transfer per 100 full-time employees for a given period of time (usually 1 year). The current list of partially exempt industries, which is included in Appendix A to Subpart B, is based on injury and illness data compiled by the Bureau of Labor Statistics (BLS) for 1997, 1998 and 1999.

OSHA is proposing to revise the list of partially exempt industries in Appendix A using the North American Industry Classification System (NAICS). The revised list in proposed Appendix A is based on DART rates compiled by BLS for 2007, 2008 and 2009. Industries listed in proposed Appendix A would still be required to keep records if requested to do so by BLS in connection with its Annual Survey (29 CFR 1904.42), or by OSHA in connection with its Data Initiative (29 CFR 1904.41).

OSHA is also proposing to revise Section 1904.39, which currently requires an employer to report to OSHA, within eight hours, all work-related fatalities and in-patient hospitalizations of three or more employees. The proposed rule would require an employer to report to OSHA, within eight hours, all work-related fatalities and all work-related in-patient hospitalizations; and within 24 hours, all work-related amputations.

This regulation was developed in accordance with the principles of Executive Order 12866 and Executive Order 13563. Executive Order 12866 requires that OSHA estimate the benefits, costs, and net benefits of proposed regulations. The Agency estimates the regulation will cost approximately $8.5 million, on an annualized basis. As discussed elsewhere in this preamble, the Agency believes the annual benefits, while unquantified, are significantly in excess of the annual costs.

I. Legal Authority

OSHA is issuing this proposed revision of the Recordkeeping regulation pursuant to authority expressly granted by sections 8 and 24 of the Occupational Safety and Health Act (the ''OSH Act'' or ''Act) (29 U.S.C. 657, 673). Section 8(c)(1) requires each employer to ''make, keep and preserve, and make available to the Secretary [of Labor] or the Secretary of Health and Human Services, such records regarding his activities relating to this Act as the Secretary, in cooperation with the Secretary of Health and Human Services, may prescribe by regulation as necessary or appropriate for the enforcement of this Act or for developing information regarding the causes and prevention of occupational accidents and illnesses.'' Section 8(c)(2) directs the Secretary to prescribe regulations ''requiring employers to maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job'' (29 U.S.C. 657(c)(2). Section 8(g)(2) of the OSH Act broadly empowers the Secretary to ''prescribe such rules and regulations as [s]he may deem necessary to carry out [her] responsibilities under the Act'' (29 U.S.C. 657(g)(2)).

Section 24 of the OSH Act contains a similar grant of authority. It requires the Secretary to ''develop and maintain an effective program of collection, compilation, and analysis of occupational safety and health statistics '' and ''compile accurate statistics on work injuries and illnesses which shall include all disabling, serious, or significant injuries and illnesses, whether or not involving loss of time from work, other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job'' (29 U.S.C. 673(a)). Section 24 also requires employers to ''file such reports [of work injuries and illnesses] with the Secretary'' as she may prescribe by regulation (29 U.S.C. 673(e)).

In addition, the Secretary's responsibilities under the OSH Act are defined largely by its enumerated purposes, which include ''[p]roviding appropriate reporting procedures that will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problem'' (29 U.S.C. 651(b)(12)).

The OSH Act authorizes the Secretary to issue two types of occupational safety and health rules; *standards* and *regulations.* Standards, which are authorized by section 6 of the OSH Act, specify remedial measures to be taken to prevent and control employee exposure to identified occupational hazards; while regulations are the means to effectuate other statutory purposes, including the collection and discrimination of records of occupational injuries and illnesses. Courts of appeal have held that OSHA recordkeeping rules are regulations and not standards (*Louisiana Chemical Ass'n* v. *Bingham, 657 F.2d 777, 782–785 (5th Cir. 1981); Workplace Health & Safety Council* v. *Reich,* 56 F.3d 1465, 1467–1469 (DC Cir. 1995).

II. Summary and Explanation of the Proposed Rule

A. Section 1904.2—Partial Exemption for Establishments in Certain Industries

Background

Although the OSH Act gives OSHA the authority to require all employers covered by the Act to keep records of employee injuries and illnesses, major classes of employers are partially exempted from Part 1904. First, as provided in Section 1904.1, employers with 10 or fewer employees are partially exempt from keeping OSHA injury and illness records. Second, as provided in section 1904.2, establishments in certain lower-hazard industry classifications are also partially exempt.

The partial exemption based on lower-hazard industry classification has been part of the OSHA recordkeeping regulations since 1982. OSHA exempted establishments in a number of service, finance, and retail industries from the duty to regularly maintain the OSHA Log and Incident Report (47 FR 57699). This industry exemption to recordkeeping requirements was intended to ''reduce paperwork burden on employers without compromising worker safety and health.'' See, 47 FR 57700.

The 1982 list of partially exempt industries was established by identifying major industry groups with relatively low rates of occupational injuries and illnesses in the SIC codes encompassing retail trade, finance, insurance and real estate, and the service industries (SICs 52–89). Major industry groups were defined at the 2-digit classification level from the SIC manual published by the U.S. Office of Management and Budget (OMB). Industries in these major industry groups were partially exempted from coverage by Part 1904 if their average lost workday injury (LWDI) rate for 1978–80 was at or below 75 percent of the overall private sector annual LWDI rate. Industries that involved more serious occupational hazards, comprising the industry divisions of agriculture, construction, manufacturing, utilities, mining, and wholesale trade, remained subject to the full recordkeeping requirements. Although the 1982 **Federal Register** notice discussed the possibility of revising the exempt industry list on a routine basis, the list remained unchanged until 2001.

On January 19, 2001, OSHA published a final rule (66 FR 5916) which comprehensively revised the Part 1904 recordkeeping regulations. As part of this revision, OSHA updated the list of lower-hazard industries that are partially exempted from the recordkeeping requirements. The list of lower-hazard industries established in the 2001 final rule is the current list set forth in Appendix A to Subpart B.

The 2001 final rule updated the 1982 list of industries by applying the same approach for identifying affected industries. Industries were selected for the list based on two criteria. First, only industries classified in SIC codes 52 through 89 were considered eligible for inclusion on the list. Second, industries were included if they had an average DART rate, based on the most recent three years of available data, at or below 75 percent of the most recent national rate. The 2001 list differed from the 1982 list in two respects: (1) The injury/illness rate data supporting the final rule's industry exemption were based on BLS statistics for 1996, 1997, and 1998, and (2) the industries were defined at the 3-digit rather than 2-digit SIC code level.

The issue of converting from SIC to NAICS codes was addressed in the 2001 rulemaking (66 FR 5916). Although the NAICS had been formally adopted by 2001, several statistical agencies had not converted their systems to the new codes. In fact, BLS did not publish its first occupational injury and illness rates using the NAICS codes until 2004, when it published the rates for calendar year 2003. As a result, OSHA stated in the preamble to the 2001 final rule that it used the SIC system to determine the list of partially exempted industries. The agency also stated its intention to conduct a future rulemaking to update the list using NAICS codes. (66 FR 5944).

Presently, NAICS is the standard system used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. economy. NAICS was developed under the auspices of OMB, and adopted in 1997 to replace the SIC system. It was developed jointly by the United States, Canada, and Mexico to allow for a high level of compatibility in business statistics among the North American countries.

The official 2007 U.S. NAICS Manual includes definitions for each industry, background information, tables showing changes between 2002 and 2007, and a comprehensive index. The official 2007 NAICS Manual is available in print and CD Rom from the National Technical Information Service (NTIS) at (800) 553–6847, or through the NTIS Web site at *http://www.ntis.gov.*

Description of Proposed Revisions

OSHA proposes to update Appendix A to Subpart B in two ways. First, the list of partially exempted industries would be converted from one based on SIC codes to one based on NAICS codes. Second, the DART rates used to determine which NAICS code industries qualify for the lower-hazard partial exemption would be based on more recent BLS data.

Consistent with OSHA's longstanding policy, individual industry classifications in major industry sectors generally considered to involve greater occupational hazards, are not included on the proposed partially exempt list. As with the current regulation, industries ineligible for the partial exemption under the proposed rule include those in the agriculture, utilities, construction, manufacturing, and wholesale trade sectors.

For industries in the remaining sectors, the most recent three years (2007, 2008 and 2009) of available BLS data were used to calculate the average rate of serious injuries and illnesses for each industry, as represented by the DART rate. Industries with an average DART rate equal to or less than 75 percent of the average national DART rate from 2007 through 2009 are included on the list of partially exempt lower-hazard industries in proposed Appendix A, with one exception.

Under the existing regulation, establishments in Personnel Supply Services (SIC 736) are currently required to maintain injury and illness logs; this industry is not included in the existing Appendix A. For many employees working for establishments in this industry, their actual place of work may be in an establishment that is part of another industry. OSHA is proposing that establishments in the corresponding NAICS industry, NAICS 5613 Employment Services, continue to

be required to maintain logs for the employees under their supervision as they are currently required to do. Thus, NAICS 5613 Employment Services is not included in the proposed Appendix A.

According to the data published by BLS, the average national private sector DART rate for 2007–2009 was 2.0. Thus, specific industries, as defined by 4-digit NAICS codes, which had an average DART rate for 2007–2009 of 1.5 or less, and which are in the eligible broad industry sectors, were included in the list in proposed Appendix A (except NAICS 5613 Employment Services).

The industries included in proposed Appendix A were identified as follows.

NAICS Code	Industry
4412	Other Motor Vehicle Dealers.
4431	Electronics and Appliance Stores.
4461	Health and Personal Care Stores.
4471	Gasoline Stations.
4481	Clothing Stores.
4482	Shoe Stores.
4483	Jewelry, Luggage, and Leather Goods Stores.
4511	Sporting Goods, Hobby, and Musical Instrument Stores.
4512	Book, Periodical, and Music Stores.
4531	Florists.
4532	Office Supplies, Stationery, and Gift Stores.
4812	Nonscheduled Air Transportation.
4861	Pipeline Transportation of Crude Oil.
4862	Pipeline Transportation of Natural Gas.
4869	Other Pipeline Transportation.
4879	Scenic and Sightseeing Transportation, Other.
4885	Freight Transportation Arrangement.
5111	Newspaper, Periodical, Book, and Directory Publishers.
5112	Software Publishers.
5121	Motion Picture and Video Industries.
5122	Sound Recording Industries.
5151	Radio and Television Broadcasting.
5172	Wireless Telecommunications Carriers (except Satellite).
5173	Telecommunications Resellers.
5179	Other Telecommunications.
5181	Internet Service Providers and Web Search Portals.
5182	Data Processing, Hosting, and Related Services.
5191	Other Information Services.
5211	Monetary Authorities—Central Bank.
5221	Depository Credit Intermediation.
5222	Nondepository Credit Intermediation.
5223	Activities Related to Credit Intermediation.
5231	Securities and Commodity Contracts Intermediation and Brokerage.
5232	Securities and Commodity Exchanges.
5239	Other Financial Investment Activities.
5241	Insurance Carriers.
5242	Agencies, Brokerages, and Other Insurance Related Activities.
5251	Insurance and Employee Benefit Funds.
5259	Other Investment Pools and Funds.
5312	Offices of Real Estate Agents and Brokers.
5331	Lessors of Nonfinancial Intangible Assets (except Copyrighted Works).
5411	Legal Services.
5412	Accounting, Tax Preparation, Bookkeeping, and Payroll Services.
5413	Architectural, Engineering, and Related Services.
5414	Specialized Design Services.
5415	Computer Systems Design and Related Services.
5416	Management, Scientific, and Technical Consulting Services.
5417	Scientific Research and Development Services.
5418	Advertising and Related Services.
5511	Management of Companies and Enterprises.
5611	Office Administrative Services.
5614	Business Support Services.
5615	Travel Arrangement and Reservation Services.
5616	Investigation and Security Services.
6111	Elementary and Secondary Schools.
6112	Junior Colleges.
6113	Colleges, Universities, and Professional Schools.
6114	Business Schools and Computer and Management Training.
6115	Technical and Trade Schools.
6116	Other Schools and Instruction.

NAICS Code	Industry
6117	Educational Support Services.
6211	Offices of Physicians.
6212	Offices of Dentists.
6213	Offices of Other Health Practitioners.
6214	Outpatient Care Centers.
6215	Medical and Diagnostic Laboratories.
6244	Child Day Care Services.
7114	Agents and Managers for Artists, Athletes, Entertainers, and Other Public Figures.
7115	Independent Artists, Writers, and Performers.
7213	Rooming and Boarding Houses.
7221	Full-Service Restaurants.
7222	Limited-Service Eating Places.
7224	Drinking Places (Alcoholic Beverages).
8112	Electronic and Precision Equipment Repair and Maintenance.
8114	Personal and Household Goods Repair and Maintenance.
8121	Personal Care Services.
8122	Death Care Services.
8131	Religious Organizations.
8132	Grantmaking and Giving Services.
8133	Social Advocacy Organizations.
8134	Civic and Social Organizations.
8139	Business, Professional, Labor, Political, and Similar Organizations.

For a more thorough discussion regarding the specific industries which would be newly exempted or newly covered by the proposed rule, please refer to Section III of this preamble.

This rulemaking also fulfills a commitment made by OSHA to the Government Accountability Office (GAO). In October 2009, GAO published a report entitled: ''Enhancing OSHA's Records Audit Process Could Improve the Accuracy of Worker Injury and Illness Data'' (GAO–10–10). One of the recommendations made by GAO was to update the list of industries used by OSHA to select worksites for records audits. In its response to GAO, OSHA agreed to conduct a rulemaking that would update the coverage of the relevant recordkeeping requirements from the old SIC-based system to one based on the NAICS codes.

In conjunction with any final rule resulting from this rulemaking that may result in some establishments being newly required to comply with OSHA recordkeeping requirements, OSHA will conduct outreach and training, and offer other types of compliance assistance, to facilitate compliance and help ensure more complete and accurate recording and reporting. OSHA welcomes suggestions from the public regarding the types of outreach, training, and assistance that would be particularly helpful.

Issues and Potential Alternatives

OSHA welcomes comments and data from the public regarding any aspect of the proposed lower-hazard industry partial exemption. More specifically, the following questions and issues are relevant to this rulemaking:

1. Should any additional industries be exempt from any of the recordkeeping requirements in Part 1904?

2. Should OSHA base partial exemptions on more detailed or more aggregated industry classifications, such as two-digit, three-digit, or six-digit NAICS codes?

3. Which industry sectors, if any, should be ineligible for partial exemption?

4. Instead of using an average DART rate of 75 percent of the most recent national DART rate, is there a better way to determine which industries should be included in Appendix A?

5. Should OSHA consider numbers of workers injured or made ill in each industry in addition to industry injury/illness rates in determining eligibility for partial exemption?

6. Are there any other data that should be applied as additional or alternative criteria for purposes of determining eligibility for partial exemption?

7. Should OSHA regularly update the list of lower-hazard exempted industries? If so, how frequently should the list be updated?

8. Are there any specific types of training, education, and compliance assistance OSHA could provide that would be particularly helpful in facilitating compliance with the recordkeeping requirements?

B. Section 1904.39—Reporting Fatality, In-Patient Hospitalization, and Amputation Incidents to OSHA

Background

Virtually since its inception, OSHA has required employers to report certain incidents involving employee fatality or hospitalization. The regulatory requirements adopted in 1971 in 29 CFR 1904.8 required employers to report, within 48 hours after the occurrence, work-related incidents resulting in at least one fatality or the hospitalization of at least five employees.

In 1994, the Agency revised its reporting requirements to require employers to report to OSHA, within eight hours, work-related events or exposures involving fatalities or the in-patient hospitalization of three or more employees (59 FR 15594). OSHA stated in the preamble to the final rule that more prompt reporting enables OSHA to inspect the site of the incident and interview personnel while their recollections are immediate, fresh and untainted by other events, thus providing more timely and accurate information about possible causes of the incident. See, 59 FR 15595. The requirements from the 1994 rulemaking have remained substantially unchanged since then, and are currently codified at 29 CFR 1904.39.

Description of Proposed Revisions

The proposed rule would require employers to report to OSHA, within eight hours, work-related incidents that result in the death of an employee or in

the in-patient hospitalization of one or more employees, and within 24 hours, a work-related amputation suffered by an employee. The proposed revision is intended to provide information necessary to help ensure America's workers have safe and healthful workplaces.

Prompt investigation of incidents causing serious injury is a key element in OSHA's ability to enforce existing standards, evaluate the effectiveness of current standards, and identify a need for new standards. OSHA believes that the eight-hour requirement for work-related fatalities, the eight-hour requirement for work-related in-patient hospitalizations, and the 24-hour requirement for amputations will enable the additional potential benefits of reporting to be realized without creating unreasonable burdens on employers.

Making all in-patient hospitalizations and amputations reportable will provide OSHA with additional information on the causes of workplace incidents and lead to greater prevention of injuries. The additional information would be obtained cost-effectively, involve relatively minimal burdens on employers, and would provide OSHA with critical information to facilitate the timely investigation of harmful incidents and quick mitigation of hazards. The information will also help OSHA target scarce resources to the most dangerous workplaces and to prevent future injuries at these workplaces.

OSHA believes that the value of this additional information easily justifies the relatively minor additional reporting burden estimated to be an average of 15 minutes per reported incident. See Section III of this preamble for a more detailed discussion of the estimated compliance costs.

The hospitalization of a worker due to a work-related incident is a serious and significant event. Requiring the reporting of every in-patient hospitalization would ensure that OSHA will be informed about many more of these serious occurrences. Greater awareness regarding the extent and nature of such cases helps in the development and prioritization of various OSHA enforcement programs and initiatives. It also serves the public interest by enabling OSHA to more effectively and efficiently target occupational safety and health hazards.

Another benefit associated with the expansion of the reporting requirements would be the increased value and utility of the resulting data. Incidents involving an in-patient hospitalization or an amputation often involve serious hazards. The proposed reporting requirements would help establish a comprehensive database that would more accurately reflect hazards that cause hospitalizations and amputations as well as identify the associated industries, processes, and other relevant factors. Such a database could prove especially useful for study and research into the causes and prevention of occupational hazards.

For purposes of OSHA recordkeeping, in-patient hospitalization occurs when a person is ''formally admitted'' to a hospital or clinic for at least one overnight stay. Out-patient treatment generally refers to patients that are seen by a physician or other licensed health care professional and leave the hospital the same day. Of course, in order for in-patient hospitalization to be reportable, the injury or illness must be work-related as defined by Section 1904.5.

The proposed reporting requirements would apply only to work-related deaths, in-patient hospitalizations, and amputations occurring within 30 days of a work-related incident. As provided in proposed paragraph (b)(7) of section 1904.39, employers would generally not be required to report fatalities, hospitalizations, or amputations of which they were not aware.

The proposed addition of amputations to the reporting requirements would ensure that these incidents involving serious injury are promptly reported. Amputations include some of the most serious types of injuries and tend to result in a greater number of lost workdays than most other injuries. According to data available from BLS for 2008, the median number of days away from work for all injuries involving days away from work was 8, while the median number of days away from work for amputations was 26. Furthermore, amputations differ from other types of serious injuries because they tend to have long-term or permanent consequences. Although information reported regarding amputations will not necessarily result in an inspection, OSHA can use this information to better target inspections to workplaces with serious hazards in order to prevent any further workplace injuries. Thus, the benefits associated with the reporting of amputations would be comparable to those associated with the reporting of hospitalizations.

For purposes of classifying occupational injuries and illnesses, amputations are defined by the Bureau of Labor Statistics in their Occupational Injury and Illness Classification Manual. An amputation is the traumatic loss of a limb or other external body part, including a fingertip. In order for an injury to be classified as an amputation, bone must be lost. Amputations include loss of a body part due to a traumatic incident, a gunshot wound, and medical amputations due to irreparable traumatic injuries. Amputations exclude traumatic injuries without bone loss and exclude enucleation (eye removal). A reportable amputation under the proposed rule would include those that occur at the workplace as well as those that occur in a hospital as a result of a work-related event.

The proposed reporting requirements would generally bring OSHA requirements more in line with those of other types of safety and health investigations. Federal regulations require aircraft pilots or operators to notify the National Transportation Safety Board (NTSB) of aviation accidents, certain incidents, and the occurrence of a variety of other conditions or events. The Federal Railroad Administration (FRA) requires railroads to report whenever they learn of the occurrence of anything on a list of types of accidents, incidents, events, or exposures.

In some states that administer their own occupational safety and health regulations, elements similar to this proposed regulation are already being enforced. For example, California requires employers to report any employee death or serious injury or illness. The phrase ''serious injury or illness'' includes the in-patient hospitalization of an employee, as well as when an employee suffers the loss of any part of the body. Alaska and Washington require notification when at least one employee is fatally injured or requires in-patient hospitalization. Utah requires notification of any disabling, serious, or significant injury, and of any occupational disease incident. In Kentucky, employers are required to report work-related incidents that result in the hospitalization of at least one employee, or in an amputation. In Oregon, incidents resulting in at least one employee needing overnight hospitalization for medical treatment are required to be reported.

Issues and Potential Alternatives

OSHA requests comments on the potential benefits and burdens associated with the proposed revisions to the reporting requirements in Section 1904.39. As noted above, under current state regulations, many businesses are already required to make reports of work-related incidents resulting in death or serious injury, and many more are already required to report all work-related in-patient hospitalizations and amputations within eight hours.

OSHA welcomes comments and data from the public regarding any aspect of the proposed reporting requirements. More specifically, the following questions and issues are relevant to this rulemaking:

1. What types of incidents and/or injuries and illnesses should be reported to OSHA and why?
2. Are there any injuries, illnesses, or conditions that should be reported to OSHA and are not included among in-patient hospitalizations?
3. Should amputations that do not result in in-patient hospitalizations be reported to OSHA?
4. Should OSHA require the reporting of all amputations?
5. Should OSHA require the reporting of enucleations?
6. Are there additional data or estimates available regarding the number of work-related incidents involving in-patient hospitalizations? Is there information available on how many work-related hospitalizations occur more than 30 days after the report of an injury or illness?
7. Should OSHA allow reports to be made by means other than a telephone, such as by e-mail, fax, or a Web-based system?
8. Are the reporting times of eight hours for fatalities, eight hours for in-patient hospitalizations, and 24 hours for amputations generally appropriate time periods for requiring reporting? What advantages or disadvantages would be associated with these or any alternative time periods?

III. Preliminary Economic Analysis and Regulatory Flexibility Certification

This proposed rule is not a ''significant regulatory action'' within the context of Executive Order 12866 or the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1532(a)), or a ''major rule'' under the Congressional Review Act (5 U.S.C. 801 *et seq.*). This rulemaking has net costs of $8.5 million and costs between $50 and $100 per affected establishment. Thus, this rulemaking imposes far less than $100 million in annual costs on the economy, and does not meet any of the other criteria specified for a significant regulatory action or major rule in Executive Order 12866, the UMRA or the Congressional Review Act.

This Preliminary Economic Analysis (PEA) addresses the costs, benefits, and economic impacts of the proposed rule. The proposed rule and the PEA were developed in accordance with the principles of Executive Order 12866 and Executive Order 13563. The proposed rule would make two changes to the existing recording and reporting requirements in Part 1904. It would change which industries are partially exempted from keeping records and would change the requirements for reporting certain work-related injuries. The affected establishments are only partially exempt because BLS may require any establishment to respond to its survey. The costs to those firms required to respond to the BLS survey are covered in the BLS survey paperwork package.

The existing regulation partially exempts all employers with 10 or fewer employees and all establishments in specific lower-hazard industry sectors from routinely keeping OSHA records. The existing industry partial exemptions were determined by identifying industries with relatively low DART rates at the 3-digit SIC code level. This proposed rule would retain the partial exemption for employers with 10 or fewer employees. It also would update the list of partially exempted industries to reflect the latest data on DART rates and to convert the industry classifications to the NAICS classification system. These changes would lead to new costs for employers who are currently partially exempt from recordkeeping requirements but would be newly required to keep records; there would also be cost savings for employers who would no longer be required to keep records.

The existing rule requires that all work-related fatalities and work-related incidents involving three or more hospitalizations be reported to OSHA within eight hours. The proposed rule would retain the requirement that all fatalities be reported to OSHA within eight hours and would require that all work-related in-patient hospitalizations be reported to OSHA within eight hours and that all work-related amputations be reported to OSHA within 24 hours. The proposed rule would thus increase the number of incidents that are to be reported to OSHA.

The remaining sections of this PEA provide estimates of the establishments that would be newly required to keep records or would be newly partially exempt from keeping records, and estimates of the numbers of reports of in-patient hospitalizations or amputations that would be required (the industrial profile section); the costs and costs savings associated with the proposed requirements; the benefits of the proposed rule; and the economic and small business impacts of the proposed changes.

Industrial Profile

The purpose of this industrial profile section is to provide information about which industries would be affected by the proposed rule, the number of affected establishments in each affected industry, employment in establishments affected by the proposed rule, and estimates of the numbers of in-patient hospitalizations and amputations that would be required to be reported by the proposed rule. (There is no need to estimate the number of fatalities to be reported as current regulations already require the reporting of fatalities.)

Partial Exemption

In regards to the partial exemption for certain lower hazard industries, OSHA identified which establishments would be newly required to keep records, and which establishments would be newly partially exempt from keeping records. This identification was complicated by the fact that the current rule classifies employers by SIC codes, a classification system dating to the 1930s which is no longer used in government statistics. OSHA had to convert employers classified by SIC code to the newer NAICS codes. In many cases, a single SIC code was divided into several NAICS codes, and conversely, a single NAICS code might contain establishments from multiple SIC codes. This analysis was conducted at the six-digit NAICS level. The data resulting from this analysis at the six-digit NAICS level are presented in the Appendix to this Preliminary Economic Analysis.

To identify those employers that would no longer be partially exempt from OSHA recordkeeping requirements under the proposed rule, OSHA examined the 1997 Economic Census: Bridge between SIC and NAICS Tables (*http://www.census.gov/epcd/naics02/S87TON02.HTM*). These tables show, for 1997, the best available data on what percentage of the establishments in each SIC code transferred into each NAICS code. Affected establishments in an SIC code exempted under the existing rule but classified in a non-exempted NAICS code under the proposed rule would be newly subject to the recordkeeping requirements. These establishments, not exempted under the proposed rule, would incur new recordkeeping costs.

Having used the bridge table to identify the portions of the industries by 6-digit NAICS code that would be newly required to keep records, OSHA used 2006 County Business Patterns to determine the corresponding numbers of establishments and employees (*http://www2.census.gov/econ/susb/data/2006/us_6digitnaics_2006.xls*). This data source provides not only the total number of establishments and employees in an industry, but also a breakdown of employees and

establishments by the size of the firm that owns the establishment. These data permit a straightforward calculation of the number of establishments with 10 or more employees. However, both the current and proposed rules cover employers with 11 or more employees. To deduct those employers with exactly 10 employees, OSHA estimated that employers with exactly ten employees represent one tenth of all employers with between 10 and 19 employees. This approach will overestimate the number of covered firms because there tend to be a more than proportional number of firms at smaller size classes.

OSHA then estimated the number of affected establishments and employees in each industry by multiplying the total number of establishments and employees in the industry by the percentage of affected establishments that were identified using the SIC—NAICS bridge tables as described above.

OSHA then estimated the number of newly recordable injuries and illnesses by dividing the number of injuries and illness recorded per industry by BLS in 2006 (BLS *http://www.bls.gov/iif/oshbulletin2006.htm*) by the total employment in the industry, and multiplied the resulting rate by the number of affected employees in the industry as derived using the 1997 SIC–NAICS bridge tables. OSHA used BLS data at the four-digit NAICS level since more detailed injury and illness data were not available for all NAICS codes.

Table III–1 presents data for the industries with establishments that would be newly required to keep records. The table shows the four-digit NAICS code, industry name, the number of affected establishments, the number of affected employees, and an estimate of the number of recordable injuries and illnesses, based on historical data, for newly affected employers. OSHA estimates that as a result of the proposed rule's revision to partial exemptions, 199,000 establishments with 5.3 million employees not previously required to record injuries would need to do so and that those establishments are would record an estimated 173,000 injuries and illnesses per year.

Having used the bridge table to identify the portions of the NAICS code industries that would be newly required to keep records, OSHA used the same methodology and data sources described above to determine the number of establishments, employees, and injuries and illnesses for establishments who would no longer be required to regularly keep records. Table III–2 shows the four-digit NAICS code, industry name, number of affected establishments, number of affected employees, and the estimated number of injuries and illnesses that would no longer be recorded in each affected industry. OSHA estimates that as a result of the revision to the list of partially exempt industries, 119,000 establishments with 4.0 million employees and an estimated 76,000 injuries and illnesses per year would no longer need to keep records regularly.

TABLE III–1— INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY REQUIRED TO KEEP RECORDS

NAICS Code	Title of NAICS Code	Affected employment	Affected establishments	Affected firms	Estimated injuries and illnesses
3118	Bakeries and Tortilla Manufacturing	42,294	1,932	1,766	571
4411	Automobile Dealers	1,204,566	23,351	19,156	48,989
4413	Automotive Parts, Accessories, and Tire Stores	5,207	426	84	204
4441	Building Material and Supplies Dealers	260,363	21,310	4,215	18,577
4452	Specialty Food Stores	88,133	7,339	3,044	2,759
4453	Beer, Wine, and Liquor Stores	69,011	6,109	2,878	2,356
4539	Other Miscellaneous Store Retailers	160,152	11,505	4,301	4,611
4543	Direct Selling Establishments	1,569	69	43	67
5313	Activities Related to Real Estate	490,941	19,341	9,881	13,864
5322	Consumer Goods Rental	130,839	14,186	1,158	1,114
5324	Commercial and Industrial Machinery and Equipment Rental and Leasing.	13,963	807	295	676
5419	Other Professional, Scientific, and Technical Services.	249,160	10,889	3,770	1,853
5612	Facilities Support Services	162,384	3,293	865	8,955
5617	Services to Buildings and Dwellings	2,140	104	50	134
5619	Other Support Services	308,984	6,238	4,152	8,150
6219	Other Ambulatory Health Care Services	105,656	2,688	859	5,734
6241	Individual and Family Services	995,856	30,230	15,915	20,988
6242	Community Food and Housing, and Emergency and Other Relief Services.	138,272	7,369	4,258	3,536
7111	Performing Arts Companies	116,043	1,994	1,864	4,483
7113	Promoters of Performing Arts, Sports, and Similar Events.	93,738	1,183	973	2,421
7121	Museums, Historical Sites, and Similar Institutions.	77,933	1,610	1,352	2,860
7139	Other Amusement and Recreation Industries	73,447	2,912	2,244	1,254
7223	Special Food Services	510,294	22,379	3,802	18,164
8129	Other Personal Services	42,254	1,498	1,117	914
Total		5,343,199	198,763	88,040	173,233

Source: OSHA, Office of Regulatory Analysis.

Source: 2006 County Business Patterns: *http://www2.census.gov/econ/susb/data/2006/us_6digitnaics_2006.xls.*

Source: 2006 Bureau of Labor Statistics, U.S. Department of Labor, Survey of Occupational Injuries and Illnesses, in cooperation with participating State agencies. *http://www.bls.gov/iif/oshwc/osh/os/osnr0028.pdf.*

TABLE III–2: INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY PARTIALLY EXEMPT FROM KEEPING RECORDS

NAICS Code	Title of NAICS Code	Affected employment	Affected establishments	Affected firms	Estimated injuries and illnesses
4412	Other Motor Vehicle Dealers	80,441	3,794	2,594	3,757
4431	Electronics and Appliance Stores	66,902	3,699	1,702	1,538
4461	Health and Personal Care Stores	15,620	1,440	425	244
4471	Gasoline Stations	128,972	12,220	2,575	3,634
4511	Sporting Goods, Hobby, and Musical Instrument Stores.	1,271	65	16	37
4532	Office Supplies, Stationery, and Gift Stores.	98,855	4,626	873	2,160
4812	Nonscheduled Air Transportation	37,807	763	580	855
4861	Pipeline Transportation of Crude Oil	7,472	352	35	175
4862	Pipeline Transportation of Natural Gas	22,080	1,303	68	510
4869	Other Pipeline Transportation	9,348	881	51	219
4879	Scenic and Sightseeing Transportation, Other.	2,155	45	39	80
4885	Freight Transportation Arrangement	166,549	7,126	2,709	3,045
5111	Newspaper, Periodical, Book, and Directory Publishers.	654,211	10,912	4,896	16,037
5122	Sound Recording Industries	14,059	426	197	206
5151	Radio and Television Broadcasting	251,523	7,186	2,084	4,931
5172	Wireless Telecommunications Carriers (except Satellite).	236,243	10,087	530	2,274
5173	Telecommunications Resellers	27,652	800	533	499
5179	Other Telecommunications	9,365	204	104	191
5181	Internet Service Providers and Web Search Portals.	20,957	210	157	174
5191	Other Information Services	10,406	211	96	164
5221	Depository Credit Intermediation	81,130	5,063	356	640
5239	Other Financial Investment Activities	8,158	115	77	19
5241	Insurance Carriers	8,946	251	55	63
5259	Other Investment Pools and Funds	20,268	924	226	129
5413	Architectural, Engineering, and Related Services.	31,953	1,144	1,008	508
5416	Management, Scientific, and Technical Consulting Services.	80,566	1,651	927	440
5418	Advertising and Related Services	48,061	1,096	764	691
5511	Management of Companies and Enterprises.	1,015,532	14,229	6,983	20,526
5614	Business Support Services	166,454	2,937	2,172	1,868
5615	Travel Arrangement and Reservation Services.	167,398	7,106	2,054	1,385
5616	Investigation and Security Services	6,361	386	332	148
6116	Other Schools and Instruction	49,500	2,142	1,961	372
7213	Rooming and Boarding Houses	6,313	350	280	60
8112	Electronic and Precision Equipment Repair and Maintenance.	61,789	2,047	1,182	1,179
8114	Personal and Household Goods Repair and Maintenance.	42,582	2,131	1,146	1,163
8122	Death Care Services	24,515	1,730	551	606
8134	Civic and Social Organizations	131,301	4,233	3,141	2,473
8139	Business, Professional, Labor, Political, and Similar Organizations.	148,056	5,490	4,648	2,788
Total		3,960,772	119,374	48,123	75,787

Source: OSHA, Office of Regulatory Analysis.
Source: 2006 County Business Patterns: *http://www2.census.gov/econ/susb/data/2006/us_6digitnaics_2006.xls.*
Source: 2006 Bureau of Labor Statistics, U.S. Department of Labor, Survey of Occupational Injuries and Illnesses, in cooperation with participating State agencies. *http://www.bls.gov/iif/oshwc/osh/os/osnr0028.pdf.*

Reporting of Fatalities, In-Patient Hospitalizations and Amputations

The proposed rule would require employers to report all work-related in-patient hospitalizations and amputations to OSHA. This requirement would affect all industries, all employers, and all 7.5 million establishments in OSHA's jurisdiction. Because OSHA already requires the reporting of work-related fatalities, this economic analysis focuses on the proposed new requirement for reporting all work-related in-patient hospitalization and amputations. The current regulation also requires the reporting of hospitalizations of three or more workers. The number of such multiple hospitalizations represents a trivial portion of all in-patient hospitalizations (For example, in Fiscal Year 2010, there were a total of 14 such reports. *http://www.osha.gov/dep/fatcat/fatcat_regional_rpt_*

09252010.html). OSHA therefore proceeded to estimate the total number of work-related in-patient hospitalizations without deducting the number of multiple hospitalizations that already must be reported.

It is difficult to estimate the number of in-patient hospitalizations that would need to be reported under the proposed rule. NIOSH has estimated that in 2004, a total of 68,000 work-related Emergency Department visits resulted in hospitalization (MMWR Weekly, April 27 2007 (56(16):393–397—''Nonfatal Occupational Injuries and Illnesses—United States, 2004'' *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5616a3.htm* (*Note:* no author given). By contrast, Dembe *et al* (*Dembe AE, Mastroberti MA, Fox SE, Bigelow C, Banks SM.* Inpatient hospital care for work-related injuries and illnesses. *Am J Ind Med.* 2003 Oct; 44(4):331–42.) estimate that from 1997 to 1999 there were 210,000 in-patient hospital admissions per year paid for by workers' compensation insurance. More recent studies in Massachusetts (1996–2001) and Louisiana (1998–2007) come up with figures ranging from 150,000 to 275,000 per year when extrapolated to the nation as a whole.

One possible reconciliation for these different estimates of work-related hospitalizations is that many workers' compensation-related hospitalizations are not emergencies but are scheduled or planned hospitalizations. This possibility is supported by the fact that musculoskeletal disorders represent only 10 percent of work-related emergency room hospitalizations in the NIOSH emergency department data, but 34 to 45 percent of hospitalizations that are paid for by workers' compensation insurance according to the workers' compensation related studies. If many of these hospitalizations are scheduled hospitalizations, they may not need to be reported as Section 1904.39 does not require reporting of fatalities, hospitalizations or amputations that occur more than 30 days after an incident has occurred. However, the rule would require the reporting of in-patient hospitalizations occurring within 30 days of the original event. Nevertheless, OSHA will use 210,000 hospitalizations per year as a preliminary estimate for purposes of examining the costs of this rule. OSHA solicits comment on the best ways to determine how many in-patient hospitalizations will fall within the scope of the proposed rule.

According to BLS, in 2008 there were 6,230 amputations that involved days away from work (*http://www.bls.gov/iif/oshwc/osh/case/osnr0033.pdf*). The more serious amputation cases will clearly require in-patient hospitalization. Because amputations frequently require hospitalization and because OSHA believes that the estimated 210,000 in-patient hospitalization reports are an overestimate of the reports that would be required by the proposed rule, OSHA believes its estimate of 210,000 reports is adequate to account for reports of both in-patient hospitalizations and amputations. OSHA solicits comment on this estimate and on potential ways to improve its accuracy.

Costs

This section presents estimates of the costs and cost savings of the proposed rule. The time requirements for the activities associated with the proposed rule have been developed through previous rulemakings and information collection requests that have been subject to extensive notice and comment. For the purposes of the analysis of the costs of this proposed rule, OSHA relied on past estimates of the time requirements for record keeping activities. (The specific past estimate relied on is cited for each time requirement estimate.)

The time requirements for various activities are estimated as follows:

Initial training of recordkeepers: one hour per establishment, applies only to currently exempt establishments that would be newly required to keep records (based on the Final Economic Analysis for the Occupational Injury and Illness Recording and Reporting Requirements, published January 19, 2001, FR 66:5916–6135).

Training of recordkeepers to account for turnover: one hour per establishment and a turnover rate of 20 percent a year resulting in an average of 0.2 hours per establishment per year. This applies to costs for currently exempt establishments that would be newly required to keep records and to cost savings for establishments that would no longer be required to keep records (based on the Final Economic Analysis for the Occupational Injury and Illness Recording and Reporting Requirements, published January 19, 2001, FR 66:5916–6135).

Completing, posting, and certifying OSHA Form 300A: 0.97 hours per establishment. This applies to costs for currently exempt establishments that would be newly required to keep records and to cost savings for establishments that would no longer be required to keep records (2008 ICR, SS 1218–0176 (1–17–08)).

Completing entries on all forms for each recordable injury and illness, accounting for privacy concerns, and providing access to records: 0.38 hours per recordable injury or illness. This applies to costs for currently exempt establishments that would be newly required to keep records and to cost savings for establishments that would no longer be required to keep records (2008 ICR, SS 1218–0176 (1–17–08).

Reporting in-patient hospitalizations or amputations: 0.25 hours per fatality or hospitalization. (2008 ICR, SS 1218–0176 (1–17–08)).

As in OSHA's PEA for the MSD column proposed rule (**Federal Register**: March 9, 2010 Volume 75, Number 45, pages 10738–10739), OSHA estimated that recordkeeping tasks will most commonly be performed by a Human Resource, Training, and Labor Relations Specialist, not elsewhere classified (Human Resources Specialist). The BLS Occupational Employment Survey (OES) indicated that in May 2008, Human Resources Specialists earned a mean hourly wage of $28 (BLS OES, 2009), with an annual salary of approximately $56,000 per year. In June 2009, the BLS National Compensation Survey indicated a mean fringe benefit factor of 1.43 for civilian workers in general. This brings the total hourly compensation (including wages and benefits) to $40.04 for Human Resources Specialists. OSHA recognizes that there is significant diversity among firms in who is charged with OSHA recordkeeping responsibilities. Smaller firms may have a bookkeeper perform this function while larger firms may use an occupational safety and health specialist. However, OSHA believes that the hourly cost of $40.04 is a reasonable estimate of the costs for the typical recordkeeper. OSHA welcomes comments on the issue of hourly compensation costs for typical recordkeepers.

Given the unit time requirements, hourly wages, the numbers of establishments and the injury and illness totals presented in Table III–1, Table III–3 shows OSHA's estimates of the costs of the proposed rule for those currently partially exempt employers who would need to keep records as a result of the proposed rule. The expected annualized cost of the rule to those employers is $13.1 million per year with the most expensive element being the completion, certification, and posting of the Form 300A with costs of $7.7 million per year. The highest cost single industry is new automobile dealers.

Given the unit time requirements, hourly wages, the number of establishments and the injury and illness totals presented in Table III–2,

Table III–4 shows OSHA's estimates of the cost savings of the proposed rule for those employers who would no longer need to keep records as a result of the proposed rule. OSHA estimates that the total cost savings for these employers would be $6.7 million per year.

TABLE III–3—ANNUALIZED COSTS TO INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY REQUIRED TO KEEP RECORDS

NAICS Code	NAICS Industry description	Learning new recordkeeping system	Relearning recordkeeping system due to turnover	Complete, certify and post OSHA Form 300A	Complete log entries, mark privacy issues and provide employees access	Total costs to industries newly required to keep records
3118	Bakeries and Tortilla Manufacturing	$11,014	$15,471	$75,037	$8,683	$110,205
4411	Automobile Dealers	133,116	186,991	906,905	745,372	1,972,385
4413	Automotive Parts, Accessories, and Tire Stores	2,430	3,413	16,553	3,108	25,503
4441	Building Material and Supplies Dealers	121,482	170,648	827,643	282,648	1,402,421
4452	Specialty Food Stores	41,837	58,769	285,031	41,981	427,618
4453	Beer, Wine, and Liquor Stores	34,824	48,918	237,251	35,842	356,834
4539	Other Miscellaneous Store Retailers	65,588	92,133	446,844	70,153	674,719
4543	Direct Selling Establishments	394	554	2,686	1,016	4,650
5313	Activities Related to Real Estate	110,259	154,883	751,181	210,948	1,227,271
5322	Consumer Goods Rental	80,874	113,604	550,982	16,955	762,414
5324	Commercial and Industrial Machinery and Equipment Rental and Leasing	4,601	6,463	31,344	10,283	52,690
5419	Other Professional, Scientific, and Technical Services	62,076	87,200	422,919	28,193	600,388
5612	Facilities Support Services	18,773	26,371	127,900	136,245	309,289
5617	Services to Buildings and Dwellings	595	836	4,053	2,032	7,516
5619	Other Support Services	35,561	49,953	242,274	124,010	451,798
6219	Other Ambulatory Health Care Services	15,321	21,522	104,383	87,247	228,474
6241	Individual and Family Services	172,337	242,084	1,174,109	319,340	1,907,869
6242	Community Food and Housing, and Emergency and Other Relief Services	42,010	59,013	286,211	53,803	441,037
7111	Performing Arts Companies	11,367	15,967	77,441	68,206	172,981
7113	Promoters of Performing Arts, Sports, and Similar Events	6,744	9,474	45,947	36,840	99,005
7121	Museums, Historical Sites, and Similar Institutions	9,181	12,896	62,546	43,514	128,137
7139	Other Amusement and Recreation Industries	16,602	23,322	113,110	19,087	172,121
7223	Special Food Services	127,578	179,211	869,174	276,368	1,452,331
8129	Other Personal Services	8,540	11,996	58,182	13,905	92,623
Totals		1,133,105	1,591,692	7,719,704	2,635,779	13,080,280

Source: OSHA, Office of Regulatory Analysis.

TABLE III–4—COST SAVINGS TO INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY PARTIALLY EXEMPT FROM RECORDKEEPING REQUIREMENTS

NAICS code	NAICS Industry description	Relearning recordkeeping system due to turnover	Complete, certify and post OSHA Form 300A	Complete log entries, mark privacy issues and provide employees access	Cost savings to industries newly exempted from keeping records
4412	Other Motor Vehicle Dealers	$30,380	$147,342	$57,160	$234,882
4431	Electronics and Appliance Stores	29,625	143,679	23,399	196,703
4461	Health and Personal Care Stores	11,533	55,936	3,719	71,188
4471	Gasoline Stations	97,861	474,627	55,292	627,780
4511	Sporting Goods, Hobby, and Musical Instrument Stores.	524	2,543	565	3,632
4532	Office Supplies, Stationery, and Gift Stores	37,046	179,672	32,867	249,585
4812	Nonscheduled Air Transportation	6,111	29,638	13,015	48,763
4861	Pipeline Transportation of Crude Oil	2,817	13,663	2,658	19,138
4862	Pipeline Transportation of Natural Gas	10,437	50,619	7,753	68,808
4869	Other Pipeline Transportation	7,053	34,209	3,325	44,588
4879	Scenic and Sightseeing Transportation, Other	356	1,728	1,214	3,299
4885	Freight Transportation Arrangement	57,062	276,750	46,329	380,141
5111	Newspaper, Periodical, Book, and Directory Publishers.	87,381	423,797	244,001	755,178
5122	Sound Recording Industries	3,415	16,561	3,127	23,102
5151	Radio and Television Broadcasting	57,541	279,076	75,027	411,645
5172	Wireless Telecommunications Carriers (except Satellite).	80,775	391,759	34,597	507,132
5173	Telecommunications Resellers	6,406	31,067	7,590	45,062
5179	Other Telecommunications	1,631	7,911	2,912	12,455
5181	Internet Service Providers and Web Search Portals.	1,679	8,144	2,653	12,477
5191	Other Information Services	1,690	8,195	2,493	12,378
5221	Depository Credit Intermediation	40,543	196,635	9,740	246,919
5239	Other Financial Investment Activities	923	4,478	283	5,684
5241	Insurance Carriers	2,012	9,759	959	12,729
5259	Other Investment Pools and Funds	7,403	35,903	4,004	47,309
5413	Architectural, Engineering, and Related Services	9,162	44,437	19,849	73,448
5416	Management, Scientific, and Technical Consulting Services.	13,221	64,121	4,190	81,532
5418	Advertising and Related Services	8,777	42,569	222,299	273,646
5511	Management of Companies and Enterprises	113,948	552,648	10,059	676,655
5614	Business Support Services	23,517	114,058	38,913	176,488
5615	Travel Arrangement and Reservation Services	56,903	275,981	7,722	340,606
5616	Investigation and Security Services	3,087	14,972	17,515	35,575
6116	Other Schools and Instruction	17,152	83,185	722	101,059
7213	Rooming and Boarding Houses	2,802	13,590	1,707	18,099
8112	Electronic and Precision Equipment Repair and Maintenance.	16,391	79,495	15,150	111,035
8114	Personal and Household Goods Repair and Maintenance.	17,062	82,751	26,979	126,792
8122	Death Care Services	13,856	67,199	49,346	130,401
8134	Civic and Social Organizations	33,901	164,421	39,480	237,802
8139	Business, Professional, Labor, Political, and Similar Organizations.	43,966	213,233	2,943	260,141
Totals		955,949	4,636,351	1,091,556	6,683,856

Source: OSHA, Office of Regulatory Analysis.

To estimate the costs of reporting in-patient hospitalizations and amputations, OSHA multiplied the estimated 210,000 cases per year by 0.25 hours per report and by the $40.04 per hour compensation costs of a recordkeeper. OSHA estimates that a recordkeeper or someone with equivalent salary would make this report. OSHA welcomes comment on whether such a report would typically be made by someone other than the person who normally keeps records and what the salary or job title of such a person might be. The resulting estimate of the annual cost of this provision is $2.1 million per year.

Table III–5 shows the total net costs of the proposed rule considering all three elements: Costs to currently exempt employers who would be newly required to keep records, cost savings to employers who would no longer be required to keep records, and reporting of all work-related in-patient hospitalizations and amputations. OSHA estimates that the total net costs of this proposed rule would be $8.5 million per year.

TABLE III–5—SUMMARY OF ANNUALIZED COSTS AND COST SAVINGS

Cost or cost savings element	Value
Costs to Employers Newly Required to Keep Records	$13,080,280

TABLE III–5—SUMMARY OF ANNUALIZED COSTS AND COST SAVINGS—Continued

Cost or cost savings element	Value
Cost Savings to Employers Newly Exempt From Keeping Records	6,683,856
Costs of Additional Reporting of Hospitalizations and Amputations	2,102,200
Net Costs	8,498,624

Benefits

OSHA anticipates that this proposed rule will have several benefits. First, the proposed rule will redirect recordkeeping efforts toward industries with higher DART rates, making the system more effective and efficient. While 119,000 establishments would no longer need to keep records, these establishments have an average injury and illness rate of 1.9 percent. On the other hand, the revision to the regulation adds 199,000 establishments with an average injury and illness rate of 3.2 percent. Thus, on average, establishments with higher injury and illness rates will keep and post records. As a result, the employer, the employees, and OSHA will have a better idea of the nature of the serious injuries and illnesses occurring in establishments with relatively high injury and illness rates.

The proposed requirements to report all work-related in-patient hospitalizations within eight hours and all work-related amputations within 24 hours ensure that OSHA will be able to better utilize enforcement resources by targeting resources to establishments with the most serious hazards.

The hospitalization of a worker or an amputation due to a work-related incident is a serious and significant event. Requiring the reporting of these events would ensure that OSHA will be informed about many more of these serious occurrences than it is now. Greater awareness regarding the extent and nature of such cases helps in the development and prioritization of various OSHA enforcement programs and initiatives. It also serves the public interest by enabling OSHA to more effectively and efficiently target occupational safety and health hazards.

If such improvements in information and enforcement save even one life every three to four years as a result of this proposed rule, they will more than pay for the costs associated with such notifications.

Economic Impacts

In this section, OSHA will first consider the economic impact on those firms newly required to keep records, and then turn to the economic impacts of requirements to report in-patient hospitalizations and amputations. No economic impacts are examined for those firms that are no longer required to keep records.

Partial Exemption

OSHA compared the baseline financial data with the total annualized incremental costs of compliance by computing compliance costs per establishment. Table III–6 shows that the costs per establishment range from just above $50 per establishment to a maximum of less than $100 per establishment. OSHA believes that costs of this magnitude cannot possibly affect the viability of a firm, and are thus economically feasible.

TABLE III–6—ECONOMIC IMPACTS OF INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY REQUIRED TO KEEP RECORDS

NAICS Code	NAICS Industry description	Affected establishments	Cost per affected establishment
3118	Bakeries and Tortilla Manufacturing	1,932	$57
4411	Automobile Dealers	23,351	84
4413	Automotive Parts, Accessories, and Tire Stores	426	60
4441	Building Material and Supplies Dealers	21,310	66
4452	Specialty Food Stores	7,339	58
4453	Beer, Wine, and Liquor Stores	6,109	58
4539	Other Miscellaneous Store Retailers	11,505	59
4543	Direct Selling Establishments	69	67
5313	Activities Related to Real Estate	19,341	63
5322	Consumer Goods Rental	14,186	54
5324	Commercial and Industrial Machinery and Equipment Rental and Leasing	807	65
5419	Other Professional, Scientific, and Technical Services	10,889	55
5612	Facilities Support Services	3,293	94
5617	Services to Buildings and Dwellings	104	72
5619	Other Support Services	6,238	72
6219	Other Ambulatory Health Care Services	2,688	85
6241	Individual and Family Services	30,230	63
6242	Community Food and Housing, and Emergency and Other Relief Services	7,369	60
7111	Performing Arts Companies	1,994	87
7113	Promoters of Performing Arts, Sports, and Similar Events	1,183	84
7121	Museums, Historical Sites, and Similar Institutions	1,610	80
7139	Other Amusement and Recreation Industries	2,912	59
7223	Special Food Services	22,379	65
8129	Other Personal Services	1,498	62
Totals		198,763	82

Source: OSHA, Office of Regulatory Analysis.

Reporting of Fatalities, Hospitalizations, and Amputations

Given OSHA's estimates of total costs of approximately $2 million per year across all 7.5 million business establishments in OSHA's jurisdiction, the average cost per establishment of this provision is $0.27 per establishment per year. In a typical year, most establishments will not report a single work-related hospitalization. Even for those that do, the cost will be approximately $10 per hospitalization or amputation that has to be reported. Costs of this magnitude will not affect the viability of any firm.

Regulatory Flexibility Certification

OSHA would continue to partially exempt employers with fewer than 11 employees from its recordkeeping regulations under this proposed rule. Such very small firms are affected by the revisions to this rule only insofar as they may have to report a fatality, in-patient hospitalization or amputation. This will be extremely rare for most small firms. Even when this occurs, OSHA has estimated the costs as approximately $10 per report, a sum that will not cause problems for even the smallest firms.

Most of the employers affected by the change in the partial exemption to the recordkeeping rule are small firms. Even when one considers the mix of small and large firms covered by the rule, the average costs per establishment are well under $100 per year per establishment. OSHA believes that costs of less than $100 per establishment do not represent a significant economic impact on small firms with 11 employees or more.

As a result of these considerations, in accordance with the RFA, OSHA certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities.

Section III Appendix: PEA Data at the Six Digit NAICS Level

This appendix provides supporting material developed in support of this rule at the six-digit NAICS level.

Table III–1A presents data on industries with establishments that would be newly required to keep records. The table shows the six-digit NAICS code, industry name, the number of affected employees, and an estimate of the number of recordable injuries and illnesses, based on historical data, for newly affected employers.

Table III–2A presents data on industries with establishments that would be newly partially exempt from recordkeeping. The table shows the six-digit NAICS code, industry name, number of affected establishments per industry, number of employees, and the estimated number of injuries and illnesses that would no longer be recorded in each affected industry.

Table III–3A shows OSHA's estimates of the costs of the proposed rule, at the six-digit NAICS level, for currently partially exempt employers who would need to keep records as a result of the proposed rule.

Table III–4A shows OSHA's estimates of the cost savings of the proposed rule, at the six-digit NAICS level, for those employers who would no longer need to keep records as a result of the proposed rule.

Table III–6A shows the costs per establishment at the six-digit NAICS level.

TABLE III–1A—INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY REQUIRED TO KEEP RECORDS

NAICS code	Title of NAICS code	Affected employment	Affected establishments	Affected firms	Estimated injuries and illnesses
311811	Retail Bakeries	42,294	1,932	1,766	571
441110	New Car Dealers	1,136,905	19,971	16,525	47,972
441120	Used Car Dealers	67,661	3,379	2,631	1,016
441310	Automotive Parts and Accessories Stores	5,207	426	84	204
444130	Hardware Stores	260,363	21,310	4,215	18,577
445210	Meat Markets	20,194	1,250	833	451
445220	Fish and Seafood Markets	908	44	40	20
445291	Baked Goods Stores	22,149	2,133	678	756
445292	Confectionery and Nut Stores	14,587	1,576	332	498
445299	All Other Specialty Food Stores	30,294	2,336	1,161	1,034
445310	Beer, Wine, and Liquor Stores	69,011	6,109	2,878	2,356
453910	Pet and Pet Supplies Stores	76,608	3,691	1,150	2,309
453920	Art Dealers	8,370	622	397	36
453991	Tobacco Stores	15,975	1,841	610	481
453998	All Other Miscellaneous Store Retailers (except Tobacco Stores).	59,200	5,351	2,144	1,784
454390	Other Direct Selling Establishments	1,569	69	43	67
531311	Residential Property Managers	312,261	11,737	5,378	8,942
531312	Nonresidential Property Managers	114,972	4,724	2,517	3,292
531320	Offices of Real Estate Appraisers	14,273	835	639	365
531390	Other Activities Related to Real Estate	49,435	2,045	1,346	1,264
532220	Formal Wear and Costume Rental	9,339	1,243	184	267
532230	Video Tape and Disc Rental	121,174	12,922	967	837
532299	All Other Consumer Goods Rental	326	21	8	11
532420	Office Machinery and Equipment Rental and Leasing.	5,642	343	156	273
532490	Other Commercial and Industrial Machinery and Equipment Rental and Leasing.	8,321	464	139	403
541910	Marketing Research and Public Opinion Polling	117,181	2,061	1,197	215
541921	Photography Studios, Portrait	51,450	6,020	642	664
541922	Commercial Photography	6,225	298	239	80
541930	Translation and Interpretation Services	8,935	240	193	317
541990	All Other Professional, Scientific, and Technical Services.	65,370	2,271	1,499	576
561210	Facilities Support Services	162,384	3,293	865	8,955
561790	Other Services to Buildings and Dwellings	2,140	104	50	134

TABLE III–1A—INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY REQUIRED TO KEEP RECORDS—Continued

NAICS code	Title of NAICS code	Affected employment	Affected establishments	Affected firms	Estimated injuries and illnesses
561910	Packaging and Labeling Services	54,249	805	694	1,431
561920	Convention and Trade Show Organizers	77,944	1,090	834	2,056
561990	All Other Support Services	176,791	4,343	2,624	4,663
621991	Blood and Organ Banks	61,113	1,082	222	3,317
621999	All Other Miscellaneous Ambulatory Health Care Services.	44,543	1,606	638	2,417
624110	Child and Youth Services	146,467	5,443	2,951	3,024
624120	Services for the Elderly and Persons with Disabilities.	479,601	10,944	6,653	16,239
624190	Other Individual and Family Services	369,788	13,844	6,312	1,725
624210	Community Food Services	26,674	2,208	848	713
624221	Temporary Shelters	60,422	2,636	1,880	1,565
624229	Other Community Housing Services	31,478	1,649	1,090	815
624230	Emergency and Other Relief Services	19,698	876	439	443
711110	Theater Companies and Dinner Theaters	67,614	1,114	1,013	2,612
711120	Dance Companies	8,038	167	165	311
711130	Musical Groups and Artists	34,372	615	604	1,328
711190	Other Performing Arts Companies	6,019	99	83	232
711310	Promoters of Performing Arts, Sports, and Similar Events with Facilities.	76,435	727	579	1,974
711320	Promoters of Performing Arts, Sports, and Similar Events without Facilities.	17,303	456	394	447
712110	Museums	70,539	1,377	1,184	2,589
712120	Historical Sites	7,394	234	167	271
713950	Bowling Centers	73,206	2,721	2,052	1,251
713990	All Other Amusement and Recreation Industries	241	192	191	4
722310	Food Service Contractors	403,073	19,247	853	14,347
722320	Caterers	107,221	3,132	2,949	3,817
812921	Photofinishing Laboratories (except One-Hour)	16,977	429	324	560
812922	One-Hour Photofinishing	1,457	172	82	48
812990	All Other Personal Services	23,820	897	712	306
Total		5,343,199	198,763	88,040	173,233

Source: OSHA, Office of Regulatory Analysis.
Source: 2006 County Business Patterns: *http://www2.census.gov/econ/susb/data/2006/us_6digitnaics_2006.xls.*
Source: 2006 Bureau of Labor Statistics, U.S. Department of Labor, Survey of Occupational Injuries and Illnesses, in cooperation with participating State agencies. *http://www.bls.gov/iif/oshwc/osh/os/osnr0028.pdf.*

III–2A—INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY PARTIALLY EXEMPT FROM KEEPING RECORDS

NAICS Code	Title of NAICS Code	Affected employment	Affected establishments	Affected firms	Estimated injuries and illnesses
441210	Recreational Vehicle Dealers	36,713	1,287	996	1,722
441221	Motorcycle Dealers	4,344	174	151	202
441222	Boat Dealers	29,649	1,897	1,048	1,379
441229	All Other Motor Vehicle Dealers	9,735	436	398	453
443111	Household Appliance Stores	48,606	2,770	1,490	1,376
443120	Computer and Software Stores	18,296	930	212	162
446120	Cosmetics, Beauty Supplies, and Perfume Stores.	2,830	294	21	42
446199	All Other Health and Personal Care Stores	12,790	1,146	404	202
447110	Gasoline Stations with Convenience Stores	128,972	12,220	2,575	3,634
451130	Sewing, Needlework, and Piece Goods Stores	1,271	65	16	37
453210	Office Supplies and Stationery Stores	98,855	4,626	873	2,160
481211	Nonscheduled Chartered Passenger Air Transportation.	28,094	524	422	636
481212	Nonscheduled Chartered Freight Air Transportation.	5,442	96	70	123
481219	Other Nonscheduled Air Transportation	4,271	144	88	97
486110	Pipeline Transportation of Crude Oil	7,472	352	35	175
486210	Pipeline Transportation of Natural Gas	22,080	1,303	68	510
486910	Pipeline Transportation of Refined Petroleum Products.	8,661	827	38	202
486990	All Other Pipeline Transportation	687	54	13	16
487990	Scenic and Sightseeing Transportation, Other	2,155	45	39	80
488510	Freight Transportation Arrangement	166,549	7,126	2,709	3,045

III–2A—INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY PARTIALLY EXEMPT FROM KEEPING RECORDS—Continued

NAICS Code	Title of NAICS Code	Affected employment	Affected establishments	Affected firms	Estimated injuries and illnesses
511110	Newspaper Publishers	358,841	4,969	1,945	11,451
511120	Periodical Publishers	148,126	3,515	1,651	2,186
511130	Book Publishers	77,645	1,044	755	957
511140	Directory and Mailing List Publishers	47,569	948	306	958
511191	Greeting Card Publishers	10,756	49	33	236
511199	All Other Publishers	11,275	387	206	248
512210	Record Production	947	33	29	5
512220	Integrated Record Production/Distribution	7,492	142	56	174
512230	Music Publishers	3,181	78	56	15
512290	Other Sound Recording Industries	2,439	173	56	12
515111	Radio Networks	10,868	426	199	729
515112	Radio Stations	106,849	5,003	1,408	1,968
515120	Television Broadcasting	133,807	1,756	477	2,234
517211	Paging	4,020	258	68	39
517212	Cellular and Other Wireless Telecommunications.	232,223	9,829	462	2,235
517310	Telecommunications Resellers	27,652	800	533	499
517910	Other Telecommunications	9,365	204	104	191
518112	Web Search Portals	20,957	210	157	174
519190	All Other Information Services	10,406	211	96	164
522120	Savings Institutions	81,130	5,063	356	640
522293	International Trade Financing	4,727	32	8	15
523999	Miscellaneous Financial Investment Activities	8,158	115	77	19
524130	Reinsurance Carriers	8,946	251	55	63
525910	Open-End Investment Funds	3,356	89	44	14
525930	Real Estate Investment Trusts	16,912	835	181	115
541320	Landscape Architectural Services	28,061	1,058	940	446
541360	Geophysical Surveying and Mapping Services	3,891	86	68	62
541612	Human Resources and Executive Search Consulting Services.	78,223	1,566	878	427
541614	Process, Physical Distribution, and Logistics Consulting Services.	1,141	47	16	6
541618	Other Management Consulting Services	1,201	38	33	7
541890	Other Services Related to Advertising	48,061	1,096	764	691
551114	Insurance and Employee Benefit Funds	1,015,532	14,229	6,983	20,526
561421	Pension Funds	32,711	645	501	347
561440	Health and Welfare Funds	133,744	2,291	1,671	1,522
561510	Travel Agencies	100,249	5,621	1,328	373
561520	Tour Operators	22,872	662	500	155
561599	All Other Travel Arrangement and Reservation Services.	44,278	823	227	857
561622	Locksmiths	6,361	386	332	148
611620	Sports and Recreation Instruction	49,500	2,142	1,961	372
721310	Rooming and Boarding Houses	6,313	350	280	60
811211	Consumer Electronics Repair and Maintenance	11,779	380	267	225
811212	Computer and Office Machine Repair and Maintenance.	4,814	136	74	92
811213	Communication Equipment Repair and Maintenance.	13,015	479	313	248
811219	Other Electronic and Precision Equipment Repair and Maintenance.	32,181	1,052	528	614
811411	Home and Garden Equipment Repair and Maintenance.	2,165	146	111	59
811412	Appliance Repair and Maintenance	22,039	883	375	602
811430	Footwear and Leather Goods Repair	43	5	2	1
811490	Other Personal and Household Goods Repair and Maintenance.	18,334	1,096	658	501
812220	Cemeteries and Crematories	24,515	1,730	551	606
813410	Civic and Social Organizations	131,301	4,233	3,141	2,473
813930	Labor Unions and Similar Labor Organizations	137,786	5,145	4,307	2,595
813940	Political Organizations	10,270	345	341	193
Totals		3,960,772	119,374	48,123	75,787

Source: OSHA, Office of Regulatory Analysis.

[1] *Source:* 2006 County Business Patterns: *http://www2.census.gov/econ/susb/data/2006/us_6digitnaics_2006.xls.*

[2] *Source:* 2006 Bureau of Labor Statistics, U.S. Department of Labor, Survey of Occupational Injuries and Illnesses, in cooperation with participating State agencies. *http://www.bls.gov/iif/oshwc/osh/os/osnr0028.pdf.*

TABLE III–3A—ANNUALIZED COSTS TO INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY REQUIRED TO KEEP RECORDS

NAICS Code	NAICS Industry description	Learning new recordkeeping system	Relearning recordkeeping system due to turnover	Complete, certify and post OSHA Form 300A	Complete log entries, mark privacy issues and provide employees access	Total costs to industries newly required to keep records
311811 ..	Retail Bakeries	$11,014	$15,471	$75,037	$8,683	$110,205
441110 ..	New Car Dealers	113,852	159,930	775,661	729,910	1,779,353
441120 ..	Used Car Dealers	19,264	27,061	131,244	15,462	193,031
441310 ..	Automotive Parts and Accessories Stores.	2,430	3,413	16,553	3,108	25,503
444130 ..	Hardware Stores	121,482	170,648	827,643	282,648	1,402,421
445210 ..	Meat Markets	7,126	10,010	48,549	6,856	72,540
445220 ..	Fish and Seafood Markets	252	354	1,715	312	2,632
445291 ..	Baked Goods Stores	12,159	17,080	82,839	11,504	123,583
445292 ..	Confectionery and Nut Stores	8,985	12,622	61,216	7,576	90,399
445299 ..	All Other Specialty Food Stores ..	13,315	18,703	90,712	15,734	138,464
445310 ..	Beer, Wine, and Liquor Stores	34,824	48,918	237,251	35,842	356,834
453910 ..	Pet and Pet Supplies Stores	21,043	29,560	143,366	35,132	229,101
453920 ..	Art Dealers	3,548	4,984	24,173	547	33,252
453991 ..	Tobacco Stores	10,493	14,740	71,487	7,326	104,045
453998 ..	All Other Miscellaneous Store Retailers (except Tobacco Stores).	30,504	42,849	207,819	27,149	308,320
454390 ..	Other Direct Selling Establishments.	394	554	2,686	1,016	4,650
531311 ..	Residential Property Managers ...	66,911	93,991	455,859	136,060	752,821
531312 ..	Nonresidential Property Managers.	26,929	37,827	183,463	50,096	298,315
531320 ..	Offices of Real Estate Appraisers	4,761	6,688	32,438	5,554	49,442
531390 ..	Other Activities Related to Real Estate.	11,658	16,376	79,421	19,238	126,692
532220 ..	Formal Wear and Costume Rental.	7,088	9,957	48,292	4,060	69,397
532230 ..	Video Tape and Disc Rental	73,665	103,478	501,867	12,735	691,744
532299 ..	All Other Consumer Goods Rental.	121	170	822	160	1,273
532420 ..	Office Machinery and Equipment Rental and Leasing.	1,953	2,744	13,307	4,155	22,158
532490 ..	Other Commercial and Industrial Machinery and Equipment Rental and Leasing.	2,648	3,719	18,037	6,128	30,532
541910 ..	Marketing Research and Public Opinion Polling.	11,748	16,502	80,035	3,268	111,553
541921 ..	Photography Studios, Portrait	34,317	48,206	233,798	10,107	326,428
541922 ..	Commercial Photography	1,699	2,386	11,574	1,223	16,881
541930 ..	Translation and Interpretation Services.	1,368	1,921	9,317	4,824	17,430
541990 ..	All Other Professional, Scientific, and Technical Services.	12,945	18,185	88,195	8,771	128,096
561210 ..	Facilities Support Services	18,773	26,371	127,900	136,245	309,289
561790 ..	Other Services to Buildings and Dwellings.	595	836	4,053	2,032	7,516
561910 ..	Packaging and Labeling Services	4,587	6,443	31,250	21,773	64,053
561920 ..	Convention and Trade Show Organizers.	6,216	8,731	42,346	31,283	88,575
561990 ..	All Other Support Services	24,759	34,779	168,678	70,955	299,171

TABLE III–3A—ANNUALIZED COSTS TO INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY REQUIRED TO KEEP RECORDS

NAICS Code	NAICS Industry description	Learning new record keeping system	Relearning recordkeeping system due to turnover	Complete, certify and post OSHA Form 300A	Complete log entries, mark privacy issues and provide employees access	Total costs to industries newly required to keep records
621991 ..	Blood and Organ Banks	6,165	8,661	42,004	50,465	107,295
621999 ..	All Other Miscellaneous Ambulatory Health Care Services.	9,156	12,862	62,379	36,782	121,179
624110 ..	Child and Youth Services	31,027	43,584	211,384	46,008	332,004

TABLE III–3A—ANNUALIZED COSTS TO INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY REQUIRED TO KEEP RECORDS—Continued

NAICS Code	NAICS Industry description	Learning new record keeping system	Relearning recordkeeping system due to turnover	Complete, certify and post OSHA Form 300A	Complete log entries, mark privacy issues and provide employees access	Total costs to industries newly required to keep records
624120 ..	Services for the Elderly and Persons with Disabilities.	62,391	87,641	425,060	247,081	822,172
624190 ..	Other Individual and Family Services.	78,919	110,859	537,665	26,251	753,693
624210 ..	Community Food Services	12,587	17,682	85,756	10,843	126,869
624221 ..	Temporary Shelters	15,027	21,108	102,375	23,817	162,327
624229 ..	Other Community Housing Services.	9,400	13,204	64,041	12,408	99,053
624230 ..	Emergency and Other Relief Services.	4,996	7,018	34,038	6,735	52,788
711110 ..	Theater Companies and Dinner Theaters.	6,350	8,920	43,263	39,742	98,274
711120 ..	Dance Companies	950	1,335	6,474	4,724	13,484
711130 ..	Musical Groups and Artists	3,504	4,923	23,874	20,203	52,504
711190 ..	Other Performing Arts Companies	562	790	3,830	3,537	8,719
711310 ..	Promoters of Performing Arts, Sports, and Similar Events with Facilities.	4,143	5,819	28,224	30,040	68,226
711320 ..	Promoters of Performing Arts, Sports, and Similar Events without Facilities.	2,601	3,654	17,723	6,800	30,779
712110 ..	Museums	7,847	11,023	53,462	39,386	111,718
712120 ..	Historical Sites	1,333	1,873	9,084	4,128	16,419
713950 ..	Bowling Centers	15,511	21,788	105,673	19,028	161,999
713990 ..	All Other Amusement and Recreation Industries.	1,092	1,534	7,438	59	10,122
722310 ..	Food Service Contractors	109,725	154,132	747,542	218,299	1,229,698
722320 ..	Caterers	17,853	25,079	121,631	58,070	222,633
812921 ..	Photofinishing Laboratories (except One-Hour).	2,445	3,435	16,658	8,516	31,053
812922 ..	One-Hour Photofinishing	979	1,376	6,673	731	9,758
812990 ..	All Other Personal Services	5,116	7,186	34,851	4,658	51,811
Totals	.....	1,133,105	1,591,692	7,719,704	2,635,779	13,080,280

Sources: OSHA, Office of Regulatory Analysis.

TABLE III–4A—COST SAVINGS TO INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY PARTIALLY EXEMPT FROM RECORDKEEPING REQUIREMENTS

NAICS Code	NAICS Industry description	Relearning recordkeeping system due to turnover	Complete, certify and post OSHA Form 300A	Complete log entries, mark privacy issues and provide employees access	Costs savings to industries newly exempted from keeping records
441210	Recreational Vehicle Dealers	$10,304	$49,974	$26,206	$86,483
441221	Motorcycle Dealers	1,396	6,773	3,075	11,244
441222	Boat Dealers	15,192	73,681	20,988	109,861
441229	All Other Motor Vehicle Dealers	3,487	16,914	6,891	27,293
443111	Household Appliance Stores	22,180	107,572	20,933	150,684
443120	Computer and Software Stores	7,445	36,107	2,467	46,019
446120	Cosmetics, Beauty Supplies, and Perfume Stores.	2,353	11,412	643	14,408
446199	All Other Health and Personal Care Stores	9,180	44,524	3,076	56,780
447110	Gasoline Stations with Convenience Stores	97,861	474,627	55,292	627,780
451130	Sewing, Needlework, and Piece Goods Stores ..	524	2,543	565	3,632
453210	Office Supplies and Stationery Stores	37,046	179,672	32,867	249,585
481211	Nonscheduled Chartered Passenger Air Transportation.	4,192	20,332	9,671	34,195
481212	Nonscheduled Chartered Freight Air Transportation.	769	3,729	1,873	6,370
481219	Other Nonscheduled Air Transportation	1,150	5,577	1,470	8,197
486110	Pipeline Transportation of Crude Oil	2,817	13,663	2,658	19,138
486210	Pipeline Transportation of Natural Gas	10,437	50,619	7,753	68,808

TABLE III–4A—COST SAVINGS TO INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY PARTIALLY EXEMPT FROM RECORDKEEPING REQUIREMENTS—Continued

NAICS Code	NAICS Industry description	Relearning recordkeeping system due to turnover	Complete, certify and post OSHA Form 300A	Complete log entries, mark privacy issues and provide employees access	Costs savings to industries newly exempted from keeping records
486910	Pipeline Transportation of Refined Petroleum Products.	6,622	32,116	3,081	41,818
486990	All Other Pipeline Transportation	432	2,093	244	2,769
487990	Scenic and Sightseeing Transportation, Other	356	1,728	1,214	3,299
488510	Freight Transportation Arrangement	57,062	276,750	46,329	380,141
511110	Newspaper Publishers	39,793	192,994	174,234	407,021
511120	Periodical Publishers	28,148	136,518	33,260	197,927
511130	Book Publishers	8,359	40,540	14,567	63,466
511140	Directory and Mailing List Publishers	7,588	36,803	14,572	58,964
511191	Greeting Card Publishers	393	1,907	3,597	5,897
511199	All Other Publishers	3,100	15,034	3,770	21,905
512210	Record Production	267	1,293	69	1,629
512220	Integrated Record Production/Distribution	1,140	5,531	2,651	9,322
512230	Music Publishers	625	3,029	230	3,884
512290	Other Sound Recording Industries	1,383	6,707	177	8,267
515111	Radio Networks	3,413	16,553	11,094	31,060
515112	Radio Stations	40,066	194,322	29,948	264,336
515120	Television Broadcasting	14,062	68,201	33,985	116,248
517211	Paging	2,067	10,024	589	12,680
517212	Cellular and Other Wireless Telecommunications.	78,708	381,735	34,009	494,452
517310	Telecommunications Resellers	6,406	31,067	7,590	45,062
517910	Other Telecommunications	1,631	7,911	2,912	12,455
518112	Web Search Portals	1,679	8,144	2,653	12,477
519190	All Other Information Services	1,690	8,195	2,493	12,378
522120	Savings Institutions	40,543	196,635	9,740	246,919
523999	Miscellaneous Financial Investment Activities	923	4,478	283	5,684
524130	Reinsurance Carriers	2,012	9,759	959	12,729
525910	Open-End Investment Funds	714	3,464	1,100	5,278
525930	Real Estate Investment Trusts	6,688	32,438	2,904	42,031
541320	Landscape Architectural Services	8,472	41,088	941	50,500
541360	Geophysical Surveying and Mapping Services	691	3,349	18,908	22,948
541612	Human Resources and Executive Search Consulting Services.	12,542	60,831	95	73,468
541614	Process, Physical Distribution, and Logistics Consulting Services.	377	1,829	100	2,306
541618	Other Management Consulting Services	301	1,461	3,995	5,757
541890	Other Services Related to Advertising	8,777	42,569	222,299	273,646
551114	Corporate, Subsidiary, and Regional Managing Offices.	113,948	552,648	10,059	676,655
561421	Telephone Answering Services	5,168	25,063	21,557	51,787
561440	Collection Agencies	18,350	88,995	17,356	124,701
561510	Travel Agencies	45,012	218,309	1,296	264,617
561520	Tour Operators	5,302	25,715	4,552	35,569
561599	All Other Travel Arrangement and Reservation Services.	6,589	31,956	1,874	40,419
561622	Locksmiths	3,087	14,972	17,515	35,575
611620	Sports and Recreation Instruction	17,152	83,185	722	101,059
721310	Rooming and Boarding Houses	2,802	13,590	1,707	18,099
811211	Consumer Electronics Repair and Maintenance	3,046	14,774	1,398	19,218
811212	Computer and Office Machine Repair and Maintenance.	1,090	5,286	3,779	10,155
811213	Communication Equipment Repair and Maintenance.	3,832	18,584	9,344	31,760
811219	Other Electronic and Precision Equipment Repair and Maintenance.	8,423	40,851	629	49,902
811411	Home and Garden Equipment Repair and Maintenance.	1,172	5,682	9,157	16,011
811412	Appliance Repair and Maintenance	7,073	34,306	18	41,398
811430	Footwear and Leather Goods Repair	39	191	7,618	7,849
811490	Other Personal and Household Goods Repair and Maintenance.	8,778	42,571	10,186	61,535
812220	Cemeteries and Crematories	13,856	67,199	49,346	130,401
813410	Civic and Social Organizations	33,901	164,421	39,480	237,802
813930	Labor Unions and Similar Labor Organizations	41,204	199,841	2,943	243,988
813940	Political Organizations	2,761	13,392	0	16,153

TABLE III–4A—COST SAVINGS TO INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY PARTIALLY EXEMPT FROM RECORDKEEPING REQUIREMENTS—Continued

NAICS Code	NAICS Industry description	Relearning recordkeeping system due to turnover	Complete, certify and post OSHA Form 300A	Complete log entries, mark privacy issues and provide employees access	Costs savings to industries newly exempted from keeping records
Totals		955,949	4,636,351	1,091,556	6,683,856

Source: OSHA, Office of Regulatory Analysis.

TABLE III–6A—ECONOMIC IMPACTS OF INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY REQUIRED TO KEEP RECORDS

NAICS Code	NAICS Industry description	Affected establishments	Cost per affected establishment
311811	Retail Bakeries	1,932	$57.04
441110	New Car Dealers	19,971	89.10
441120	Used Car Dealers	3,379	57.12
441310	Automotive Parts and Accessories Stores	426	59.84
444130	Hardware Stores	21,310	65.81
445210	Meat Markets	1,250	58.03
445220	Fish and Seafood Markets	44	59.61
445291	Baked Goods Stores	2,133	57.94
445292	Confectionery and Nut Stores	1,576	57.35
445299	All Other Specialty Food Stores	2,336	59.28
445310	Beer, Wine, and Liquor Stores	6,109	58.42
453910	Pet and Pet Supplies Stores	3,691	62.07
453920	Art Dealers	622	53.43
453991	Tobacco Stores	1,841	56.53
453998	All Other Miscellaneous Store Retailers (except Tobacco Stores)	5,351	57.62
454390	Other Direct Selling Establishments	69	67.23
531311	Residential Property Managers	11,737	64.14
531312	Nonresidential Property Managers	4,724	63.15
531320	Offices of Real Estate Appraisers	835	59.20
531390	Other Activities Related to Real Estate	2,045	61.96
532220	Formal Wear and Costume Rental	1,243	55.81
532230	Video Tape and Disc Rental	12,922	53.53
532299	All Other Consumer Goods Rental	21	60.12
532420	Office Machinery and Equipment Rental and Leasing	343	64.67
532490	Other Commercial and Industrial Machinery and Equipment Rental and Leasing.	464	65.74
541910	Marketing Research and Public Opinion Polling	2,061	54.13
541921	Photography Studios, Portrait	6,020	54.23
541922	Commercial Photography	298	56.65
541930	Translation and Interpretation Services	240	72.65
541990	All Other Professional, Scientific, and Technical Services	2,271	56.41
561210	Facilities Support Services	3,293	93.92
561790	Other Services to Buildings and Dwellings	104	72.02
561910	Packaging and Labeling Services	805	79.61
561920	Convention and Trade Show Organizers	1,090	81.24
561990	All Other Support Services	4,343	68.89
621991	Blood and Organ Banks	1,082	99.21
621999	All Other Miscellaneous Ambulatory Health Care Services	1,606	75.45
624110	Child and Youth Services	5,443	61.00
624120	Services for the Elderly and Persons with Disabilities	10,944	75.12
624190	Other Individual and Family Services	13,844	54.44
624210	Community Food Services	2,208	57.46
624221	Temporary Shelters	2,636	61.58
624229	Other Community Housing Services	1,649	60.07
624230	Emergency and Other Relief Services	876	60.23
711110	Theater Companies and Dinner Theaters	1,114	88.23
711120	Dance Companies	167	80.89
711130	Musical Groups and Artists	615	85.41
711190	Other Performing Arts Companies	99	88.42
711310	Promoters of Performing Arts, Sports, and Similar Events with Facilities	727	93.89
711320	Promoters of Performing Arts, Sports, and Similar Events without Facilities	456	67.45
712110	Museums	1,377	81.16
712120	Historical Sites	234	70.20
713950	Bowling Centers	2,721	59.54
713990	All Other Amusement and Recreation Industries	192	52.86

TABLE III–6A—ECONOMIC IMPACTS OF INDUSTRIES THAT INCLUDE ESTABLISHMENTS THAT WOULD BE NEWLY REQUIRED TO KEEP RECORDS—Continued

NAICS Code	NAICS Industry description	Affected establishments	Cost per affected establishment
722310	Food Service Contractors	19,247	63.89
722320	Caterers	3,132	71.09
812921	Photofinishing Laboratories (except One-Hour)	429	72.40
812922	One-Hour Photofinishing	172	56.80
812990	All Other Personal Services	897	57.74
Totals		198,763	81.63

Source: OSHA, Office of Regulatory Analysis.

IV. OMB Review Under the Paperwork Reduction Act of 1995

This proposal would revise an existing collection of information as defined and covered by the Paperwork Reduction Act of 1995 and its implementing regulations. An ongoing information collection approved by OMB under the provisions of the Paperwork Reduction Act currently includes the type of information collected in this proposed regulation, as well as the manner in which employers collect the information. Accordingly, OMB approved the information collections associated with the requirements to maintain information on fatalities, injuries, and illnesses, and to report and submit this information to OSHA, under the Control Number 1218–0176. The current regulation at 29 CFR 1904.39 requires an employer to report to OSHA, within eight hours, all work-related fatalities and in-patient hospitalizations of three or more employees. The proposed rule would require employers to report to OSHA, within eight hours, all work-related fatalities and work-related in-patient hospitalizations (regardless of the number of employees involved), and, within 24 hours, all work-related amputations. The proposal also would update Appendix A to 29 CFR part 1904, subpart B, of its injury and illness recording and reporting regulations. Appendix A contains a list of industries that are partially exempt from maintaining records of occupational injuries and illnesses, generally due to their relatively low rates of occupational injury and illness. OSHA based the current list of industries on the Standard Industrial Classification (SIC) system. In 1997, the North American Industry Classification System (NAICS) was introduced to classify establishments by industry. The proposed rule would update Appendix A by replacing it with a list of industries based on NAICS and more recent injury and illness data.

OSHA prepared and submitted a revised Information Collection Request (ICR) for this proposed regulation to OMB for review in accordance with 44 U.S.C. 3507(d). The Agency solicits comments on the proposed revised collection of information requirements and the estimated burden hours associated with these requirements, including comments on the following items:

- Whether the proposed collection of information requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and cost) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the compliance burden on employers, for example, by using automated or other technological means for collecting and transmitting information.

As required by 5 CFR 1320.5(a)(1)(iv) and 1320.8(d)(2), the following paragraphs provide information about this ICR.

1. *Title:* 29 CFR Part 1904 Recordkeeping and Reporting Occupational Injuries and Illnesses

2. *Number of respondents:* OSHA is proposing to revise the list of partially exempt industries in Appendix A of 29 CFR 1904, subpart B, using the North American Industry Classification System (NAICS). OSHA based the revised list in proposed Appendix A on DART rates compiled by the Bureau of Labor Statistics (BLS) for 2007, 2008, and 2009. The Agency still would require industries listed in proposed Appendix A to maintain records if requested to do so by BLS in connection with its Annual Survey (see 29 CFR 1904.42), or by OSHA in connection with its Data Initiative (see 29 CFR 1904.41). OSHA estimates that, as a result of the proposed revisions to the list of industries partially exempt from the regulation, 199,000 establishments with 5.3 million employees not previously required to record the information would need to do so, and that those establishments would record an estimated 173,000 injuries and illnesses per year. The total number of respondents is 1,665,374.

2. *Frequency of responses:* Annually; on occasion.

3. *Number of responses:* 7,449,273.

4. *Average time per response:* Time per response varies from three minutes for making an entry on a confidential list of privacy-concern cases (see § 1904.29(b)(6)), to one hour to learn the requirements of the recordkeeping standard.

5. *Estimated total burden hours:* 3,355,105 hours.

6. *Estimated costs (capital-operation and maintenance):* There are no capital costs for the proposed collection of information requirements.

Members of the public may comment on the paperwork requirements in this proposed regulation by sending their written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor, OSHA (Regulation Identifier Number (RIN) 1218–AC50), Office of Management and Budget, Room 10235, Washington, DC 20503; telephone: 202–395–6929; fax: 202–395–6881 (these are not toll-free numbers); e-mail: *OIRA_submission@omb.eop.gov.* OSHA encourages commenters also to submit their comments on these paperwork requirements to the rulemaking docket along with their comments on other parts of the proposed regulation. For instructions on submitting these comments to the docket, see the sections of this **Federal Register** notice titled **DATES** and **ADDRESSES**'' Comments submitted in response to this notice are public records; therefore, OSHA cautions commenters about submitting personal information such as Social Security numbers and dates of birth. To

access the docket to read or download comments and other materials related to this paperwork determination, including the complete information collection request (ICR), use the procedures described under the section of this notice titled **ADDRESSES**. You may obtain an electronic copy of the complete ICR by visiting the Web site at *http://www.reginfo.gov/public/do/PRAMain,* then scroll under ''Currently Under Review'' to ''Department of Labor (DOL)'' to view all of the DOL's ICRs, including those ICRs submitted for proposed rulemakings. To make inquiries, or to request other information, contact Mr. Todd Owen, Directorate of Standards and Guidance, OSHA, Room N–3609, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2222. OSHA notes that a Federal agency cannot (1) conduct or sponsor a collection of information unless OMB approves it under the PRA and displays a currently valid OMB control number, and (2) require a party to respond to a collection of information unless the collection of information displays a currently valid OMB control number. Also, notwithstanding any other provision of law, no party shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number. OSHA will publish a notice of OMB's action when it publishes the final regulation.

V. Unfunded Mandates

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*), as well as Executive Order 12875, this proposed rule does not include any Federal mandate that may result in increased expenditures by state, local, and Tribal governments, or increased expenditures by the private sector of more than $100 million.

VI. Federalism

The proposed rule has been reviewed in accordance with Executive Oder 13132 (52 FR 41685), regarding federalism. Because this rulemaking involves a ''regulation'' issued under Sections 8 and 24 of the OSH Act, and is not an ''occupational safety and health standard'' issued under Section 6 of the OSH Act, the rule will not preempt state law (29 U.S.C. 667(a)). The effect of the proposed rule on states is discussed in section VIII. State Plan States.

VII. State Plan States

Consistent with Section 18 of the OSH Act (29 U.S.C. 667) and the requirements of 29 CFR 1904.37 and 1952.4, within 6 months after publication of the final OSHA rule, state-plan states must promulgate occupational injury and illness recording and reporting requirements that are the same as the Federal requirements for determining which injuries and illnesses will be entered into the records and how they are entered. All other injury and illness recording and reporting requirements that are promulgated by state-plan states may be more stringent than, or supplemental to, the Federal requirements, but, because of the unique nature of the national recordkeeping program, states must consult with OSHA and obtain approval of such additional or more stringent reporting and recording requirements to ensure that they will not interfere with uniform reporting objectives.

There are 27 state plan states and territories. The states and territories that cover private sector employers are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. Connecticut, Illinois, New Jersey, New York, and the Virgin Islands have OSHA approved state plans that apply to state and local government employees only.

VIII. Public Participation

This rulemaking is governed by the notice and comments requirements in the Administrative Procedure Act (APA)(5 U.S.C. 553) rather than section 6 of the OSH Act (29 U.S.C. 655) and 29 CFR Part 1911, which only apply to ''promulgating, modifying or revoking occupational safety and health standards'' (29 CFR part 1911). For example, section 6(b)(3) of the OSH Act and 29 CFR 1911.11 state that the requirement to hold an informal public hearing on a proposed rule only applies to rulemakings on occupational safety and health standards, not to those dealing with regulations.

Section 553(b)(1) of the APA requires the agency to specify the type of rule involved, the time during which the agency will receive comments on the proposal, and the instructions regarding the procedures for submitting comments. The APA does not specify a minimum period for submitting comments.

Public Submissions

OSHA invites comment on all aspects of the proposed rule. OSHA specifically encourages comment on the questions raised in the issues and potential alternatives sections of this preamble. Interested persons must submit comments by September 20, 2011 The Agency will carefully review and evaluate all comments, information, and data, as well as all other information in the rulemaking record, to determine how to proceed.

You may submit comments in response to this document (1) electronically at *http://www.regulations.gov,* which is the Federal e-rulemaking portal; (2) by fax; or (3) by hard copy. All submissions must identify the Agency name and the OSHA docket number (Docket No. OSHA–2010–0019) or RIN (RIN No. 1218–AC50) for this rulemaking. You may supplement electronic submissions by uploading document files electronically. If, instead, you wish to mail additional materials in reference to an electronic or fax submission, you must submit three copies to the OSHA docket office (see **ADDRESSES** section). The additional materials must clearly identify your electronic comments by name, date, and docket number, so OSHA can attach them to your comments.

Because of security-related procedures, the use of regular mail may cause a significant delay in the receipt of submissions. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger or courier service, please contact the OSHA docket office at (202) 693–2350 (TTY (877) 889–5627).

Access to Docket

Comments in response to this **Federal Register** notice are posted at *http://www.regulations.gov,* the Federal e-rulemaking portal. Therefore, OSHA cautions individuals about submitting personal information such as social security numbers and birthdates. Although submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download through that Web site. All comments and exhibits, including copyrighted material, are available for inspection and copying at the OSHA docket office. Information on using *http://www.regulations.gov* to submit comments and access dockets is available on that Web site. Contact the OSHA docket office for information about materials not available through the Web site and for assistance in using the Internet to locate docket submissions.

Electronic copies of this **Federal Register** document are available at

http://www.regulations.gov. This document, as well as news releases and other relevant information, also are available at OSHA's Web page at *http://www.osha.gov.* For specific information about OSHA's Recordkeeping rule, go the Recordkeeping page on OSHA's Web page.

IX. Authority and Signature

This document was prepared under the direction of Dr. David Michaels, Assistant Secretary for Occupational Safety and Health. It is issued under Sections 8 and 24 of the Occupational Safety and Health Act (29 U.S.C. 657, 673), 5 U.S.C. 553, and Secretary of Labor's Order 4–2010 (75 FR 55355, 9/10/2010)

List of Subjects in 29 CFR Part 1904

Health statistics, Occupational safety and health, Reporting and recordkeeping requirements.

Signed at Washington, DC on June 15, 2011.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

X. Proposed Rule

Part 1904 of Title 29 of the Code of Federal Regulations is hereby proposed to be amended as follows:

PART 1904—[AMENDED]

1. The authority citation for part 1904 continues to read as follows:

Authority: 29 U.S.C. 657, 658, 660, 666, 669, 673, Secretary of Labor's Order No. 3–2000 (65 FR 50017), and 5 U.S.C. 533.

2. Amend § 1904.2 as follows:

A. Revise paragraph (a)(1).

B. Remove paragraph (b)(1).

C. Redesignate paragraphs (b)(2) and (b)(3) as (b)(1) and (b)(2).

D. Revise newly designated paragraphs (b)(1) and (b)(2).

The revisions read as follows:

§ 1904.2 Partial exemption for establishments in certain industries.

(a) * * *

(1) If your business establishment is classified in a specific industry subsector listed in Appendix A to this Subpart B, you do not need to keep OSHA injury and illness records unless the government asks you to keep the records under § 1904.41 or § 1904.42. However, all employers must report to OSHA any workplace incident that results in a fatality, an amputation, or the in-patient hospitalization of an employee (see § 1904.39).

* * * * *

(b) * * *

(1) *Is the partial industry classification exemption based on the industry classification of my entire company or on the classification of individual business establishments operated by my company*? The partial industry classification exemption applies to individual business establishments. If a company has several business establishments engaged in different classes of business activities, some of the company's establishments may be required to keep records, while others may be exempt.

(2) *How do I determine the correct NAICS code for my business?* The NAICS was designed and documented in such a way to allow business establishments to self-code. There are a number of tools and references available to help you to determine the most appropriate NAICS code for your business from the U.S. Census Bureau at *http://www.census.gov.* You may contact your nearest OSHA office or state agency for help in determining your NAICS code.

* * * * *

3. Revise Appendix A to subpart B of part 1904 to read as follows:

Appendix A to Subpart B of Part 1904 (Non-Mandatory)—Partially Exempt Industries

Employers are not required to keep OSHA injury and illness records for any establishment classified in the following North American Industry Classification System (NAICS) codes, unless they are asked in writing to do so by OSHA, the Bureau of Labor Statistics (BLS), or a state agency operating under the authority of OSHA or the BLS. All employers, including those partially exempted by reason of company size or industry classification, must report to OSHA any workplace incident that results in a fatality, in-patient hospitalization, or amputation (see § 1904.39).

NAICS Code	Industry
4412	Other Motor Vehicle Dealers.
4431	Electronics and Appliance Stores.
4461	Health and Personal Care Stores.
4471	Gasoline Stations.
4481	Clothing Stores.
4482	Shoe Stores.
4483	Jewelry, Luggage, and Leather Goods Stores.
4511	Sporting Goods, Hobby, and Musical Instrument Stores.
4512	Book, Periodical, and Music Stores.
4531	Florists.
4532	Office Supplies, Stationery, and Gift Stores.
4812	Nonscheduled Air Transportation.
4861	Pipeline Transportation of Crude Oil.
4862	Pipeline Transportation of Natural Gas.
4869	Other Pipeline Transportation.
4879	Scenic and Sightseeing Transportation, Other.
4885	Freight Transportation Arrangement.
5111	Newspaper, Periodical, Book, and Directory Publishers.
5112	Software Publishers.
5121	Motion Picture and Video Industries.
5122	Sound Recording Industries.
5151	Radio and Television Broadcasting.
5172	Wireless Telecommunications Carriers (except Satellite).
5173	Telecommunications Resellers.
5179	Other Telecommunications.
5181	Internet Service Providers and Web Search Portals.
5182	Data Processing, Hosting, and Related Services.

NAICS Code	Industry
5191	Other Information Services.
5211	Monetary Authorities—Central Bank.
5221	Depository Credit Intermediation.
5222	Nondepository Credit Intermediation.
5223	Activities Related to Credit Intermediation.
5231	Securities and Commodity Contracts Intermediation and Brokerage.
5232	Securities and Commodity Exchanges.
5239	Other Financial Investment Activities.
5241	Insurance Carriers.
5242	Agencies, Brokerages, and Other Insurance Related Activities.
5251	Insurance and Employee Benefit Funds.
5259	Other Investment Pools and Funds.
5312	Offices of Real Estate Agents and Brokers.
5331	Lessors of Nonfinancial Intangible Assets (except Copyrighted Works).
5411	Legal Services.
5412	Accounting, Tax Preparation, Bookkeeping, and Payroll Services.
5413	Architectural, Engineering, and Related Services.
5414	Specialized Design Services.
5415	Computer Systems Design and Related Services.
5416	Management, Scientific, and Technical Consulting Services.
5417	Scientific Research and Development Services.
5418	Advertising and Related Services.
5511	Management of Companies and Enterprises.
5611	Office Administrative Services.
5614	Business Support Services.
5615	Travel Arrangement and Reservation Services.
5616	Investigation and Security Services.
6111	Elementary and Secondary Schools.
6112	Junior Colleges.
6113	Colleges, Universities, and Professional Schools.
6114	Business Schools and Computer and Management Training.
6115	Technical and Trade Schools.
6116	Other Schools and Instruction.
6117	Educational Support Services.
6211	Offices of Physicians.
6212	Offices of Dentists.
6213	Offices of Other Health Practitioners.
6214	Outpatient Care Centers.
6215	Medical and Diagnostic Laboratories.
6244	Child Day Care Services.
7114	Agents and Managers for Artists, Athletes, Entertainers, and Other Public Figures.
7115	Independent Artists, Writers, and Performers.
7213	Rooming and Boarding Houses.
7221	Full-Service Restaurants.
7222	Limited-Service Eating Places.
7224	Drinking Places (Alcoholic Beverages).
8112	Electronic and Precision Equipment Repair and Maintenance.
8114	Personal and Household Goods Repair and Maintenance.
8121	Personal Care Services.
8122	Death Care Services.
8131	Religious Organizations.
8132	Grantmaking and Giving Services.
8133	Social Advocacy Organizations.
8134	Civic and Social Organizations.
8139	Business, Professional, Labor, Political, and Similar Organizations.

* * * * *

4. Amend § 1904.39 as follows:

A. Revise paragraphs (a), (b)(1), (b)(2), (b)(3), (b)(4), (b)(6), and (b)(7).

B. Add paragraph (b)(8).

The revisions and addition should read as follows:

§ 1904.39 Reporting fatalities and multiple hospitalization incidents to OSHA.

(a) *Basic Requirement.* Within eight (8) hours after the death of any employee from a work-related incident, within eight (8) hours after the in-patient hospitalization of any employee as a result of a work-related incident, and within twenty-four (24) hours after an amputation suffered by an employee as a result of a work-related incident, you must orally report the incident by telephone or in person to the nearest Area Office of the Occupational Safety and Health Administration (OSHA), U.S. Department of Labor. You may also use the OSHA toll-free central telephone number, 1–800–321–OSHA (1–800–321–6742).

(b) * * *

(1) *If the Area Office is closed, may I report the incident by leaving a message on OSHA's answering machine, faxing the area office, or sending an e-mail?* No, if you can't talk to a person at the Area Office, you must report the fatality, in-patient hospitalization, or

amputation incident using the 800 number.

(2) *What information do I need to give to OSHA about the incident?* You must give OSHA the following information for each fatality, in-patient hospitalization, or amputation incident:

(i) The establishment name;

(ii) The location of the incident;

(iii) The time of the incident;

(iv) The number of fatalities or hospitalized employees or amputations;

(v) The names of any injured employees;

(vi) Your contact person and his or her phone number; and

(vii) A brief description of the incident.

(3) *Do I have to report every fatality or in-patient hospitalization or amputation incident resulting from a motor vehicle accident?* No, you do not have to report all of these incidents. If the motor vehicle accident occurs on a public street or highway, and does not occur in a construction work zone, you do not have to report the incident to OSHA. However, these injuries must be recorded on your OSHA injury and illness records, if you are required to keep such records.

(4) *Do I have to report a fatality or in-patient hospitalization or amputation incident that occurs on a commercial or public transportation system?* No, you do not have to call OSHA to report a fatality or hospitalization or amputation incident if it involves a commercial airplane, train, subway, or bus accident. However, these injuries must be recorded on your OSHA injury and illness records, if you are required to keep such records.

* * *

(6) *Do I have to report a fatality or in-patient hospitalization or amputation that occurs long after the incident*? No, you must only report each fatality or in-patient hospitalization or amputation that occurs within thirty (30) days of an incident.

(7) *What if I don't learn about an incident right away?* If you do not learn of a reportable incident at the time it occurs and the incident would otherwise be reportable under paragraphs (a) and (b) of this section, you must make the report within eight (8) hours (for a fatality or an in-patient hospitalization) or twenty four (24) hours (for an amputation) of the time the incident is reported to you or to any of your agent(s) or employee(s).

(8) *What types of injuries are counted as amputations?* For purposes of classifying occupational injuries and illnesses, amputations are defined by the Bureau of Labor Statistics in their Occupational Injury and Illness Classification Manual. An amputation is the traumatic loss of a limb or other external body part, including a fingertip. In order for an injury to be classified as an amputation, bone must be lost. Amputations include loss of a body part due to a traumatic incident, a gunshot wound, and medical amputations due to irreparable traumatic injuries. Amputations exclude traumatic injuries without bone loss and exclude enucleation (eye removal).

[FR Doc. 2011–15277 Filed 6–21–11; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100 and 165

[Docket No. USCG–2008–0384]

RIN 1625–AA00; 1625–AA08; 1625–AA87

Special Local Regulations; Safety and Security Zones; Recurring Events in Captain of the Port Long Island Sound Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to remove, add, and consolidate special local regulations and establish permanent safety zones for annual recurring marine events as well as establish a permanent security zone in the Coast Guard Sector Long Island Sound Captain of the Port (COTP) Zone. When these special local regulations or safety zones are activated and subject to enforcement, this rule would restrict vessels from portions of water areas during these annual recurring events. The revised special local regulations and safety zones would expedite public notification of events, and ensure the protection of the maritime public and event participants from the hazards associated with these annual recurring events.

DATES: Comments and related material must be received by the Coast Guard on or before July 22, 2011.

Requests for public meetings must be received by the Coast Guard on or before June 29, 2011.

ADDRESSES: You may submit comments identified by docket number USCG–2008–0384 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 proposed rule, call or e-mail Petty Officer Joseph Graun, Waterways Management Division at Coast Guard Sector Long Island Sound, telephone 203–468–4544, e-mail *joseph.l.graun@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2008–0384), 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 (via *http://www.regulations.gov*) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone 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,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rule'' and insert ''USCG–2008–0384'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape 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 the rule based on your comments.

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,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2008–0384'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. 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. We have an agreement with the Department of Transportation to use the Docket Management Facility.

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).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the four methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Basis and Purpose

The legal basis for the proposed rule is 33 U.S.C. 1231, 1233; 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; Public Law 107–295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to define regulatory safety zones, security zones and special local regulations.

This regulation carries out three related actions: (1) Establishing necessary safety zones and special local regulations, (2) establishing one necessary security zone, and (3) updating and reorganizing existing regulations for ease of use and reduction of administrative overhead.

Discussion of Proposed Rule

The Coast Guard proposes to revise sections 33 CFR 165.151 and 165.154; add section 100.100. The proposed changes will remove 37 regulated areas, establish 32 new safety zones, three special local regulations, and one security zone, and consolidate and simplify these regulations. By establishing a permanent regulation containing these events, the Coast Guard will eliminate the need to establish temporary rules for events that occur on an annual basis. This provides opportunity for the public to comment while limiting the unnecessary burden of continually establishing temporary rules every year.

(1) Establishing new safety zones and special local regulations

This rule proposes to establish 32 new safety zones under 33 CFR 165.151 and three special local regulations under 33 CFR; these events are listed below in the text of the regulation. As large numbers of spectator vessels are expected to congregate around the location of these events, the regulated areas are needed to protect both spectators and participants from the safety hazards created by the event. During the enforcement period of the regulated areas, persons and vessels would be prohibited from entering, transiting through, remaining, anchoring or mooring within the zone unless specifically authorized by the COTP or the designated representative. The Coast Guard may be assisted by other Federal, State and local agencies in the enforcement of these regulated areas.

Certain safety zones and special local regulations are listed without known dates or times. Coast Guard Sector Long Island Sound will cause notice of the enforcement of these safety zones to be made by all appropriate means to affect the widest publicity among the effected segments of the public, including publication in the **Federal Register** as a Notice of Enforcement, Local Notice to Mariners and Broadcast Notice to Mariners.

(2) Establishing a New Security Zone

This rule proposes to establish a security zone in the vicinity of the Coast Guard Academy in New London, CT. This security zone would encompass all navigable waters of the Thames River within a 500-yard radius of Jacobs Rock, located at approximate position 41°22.36′N, 072°05.66′W. The security zone will not encompass the navigable channel in the Thames River, so commercial traffic would be able to pass unimpeded. This security zone would be enforced during visits by government officials and at times of heighted security threats. Entry into this zone would be prohibited unless authorized by the COTP, Long Island Sound. The COTP will notify the maritime community of periods during which this security zone will be enforced via Notice of Enforcement, Local Notice to Mariners and Marine Safety Information Radio Broadcasts.

(3) Updating and Reorganizing Existing Regulations

We have identified ten regulated areas in 33 CFR 100.114 and eight regulated areas in 33 CFR 165.151 as unnecessary. One exception is event 7.1 in Table 1, American legion Post 83 Fireworks; this event still occurs annually, however it is also regulated under 33 CFR 165.151(a)(19). These regulations are redundant in that they both protect waterway users during the event. This rule proposes to remove the event from 33 CFR 100.114(7.1) because it is unnecessarily duplicative.

In addition to removing obsolete regulations, this rule proposes to reorganize and consolidate existing Sector Long Island Sound COTP Zone marine event regulations under 33 CFR 165.151 and non-marine event safety and security zones under 33 CFR 165.154. This action will eliminate the burden and confusion caused by the current configuration of numerous individual regulations spread across two CFR parts.

(4) Miscellaneous

The regulated area established under 33 CFR 165.155 (Northville Industries Offshore Platform, Riverhead, Long Island, New York-Safety Zone) is no longer in use. The Coast Guard discussed this regulation at length with the current Terminal Manager of the offshore platform. The Terminal Manger

indicated the regulation was written when the platform had a different owner and since the current owner acquired the platform in 1992 no liquefied petroleum gas (LPG) transfers have been conducted and there are no future plans to conduct LPG transfers. The terminal manager has no objection to this regulation being removed. We therefore propose to remove 33 CFR 165.155.

Additionally, in updating 33 CFR 165.154, two areas currently designated as ''Safety and Security Zones'' in the current 33 CFR 165.154 would be re-designated simply as security zones. Changing these zones exclusively to security zones is necessary to accurately reflect their intended purpose: to protect the facility and vessels from persons or objects that could cause them harm. Dropping the word safety does not change the size, shape or effectiveness of the zone. What does change is the legal authority behind the regulation. This update is necessary to clarify the intent of and authorities used to enforce these regulations.

Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This proposed 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, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

We expect the economic impact of this proposed rule to be minimal. Although this regulation may have some impact on the public, the potential impact will be minimized for the following reasons:

The Coast Guard has previously promulgated safety zones or special local regulations, in accordance with 33 CFR Parts 100 and 165, for all event areas contained within this proposed regulation and has not received notice of any negative impact caused by any of the safety zones or special local regulations. By establishing a permanent regulation containing all of these events, the Coast Guard will eliminate the need to establish individual temporary rules for each separate event that occurs on an annual basis, thereby limiting the costs of cumulative regulations.

Vessels will only be restricted from safety zones and special local regulation areas for a short duration of time. Vessels may transit in portions of the affected waterway except for those areas covered by the proposed regulated areas. Notifications of exact dates and times of the enforcement period will be made to the local maritime community through the Local Notice to Mariners and Broadcast Notice to Mariners or through a Notice of Enforcement in the **Federal Register**. No new or additional restrictions would be imposed on vessel traffic.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This proposed rule would affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit or anchor in the designated regulated area during the enforcement periods.

The regulated areas will not have a significant economic impact on a substantial number of small entities for the following reasons: The regulated areas will be of limited size and of short duration; vessels that can safely do so may navigate in all other portions of the waterways except for the areas designated as regulated areas; these regulated areas have been promulgated in the past with no public comments submitted. Additionally, before the effective period, the Coast Guard will issue notice of the time and location of each regulated area through a Local Notice to Mariners and Broadcast Notice to Mariners.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Petty Officer Joseph Graun, Waterways Management Division at Coast Guard Sector Long Island Sound, telephone 203–468–4544, e-mail *joseph.l.graun@uscg.mil.* The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice

Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

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

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

Environment

We have analyzed this proposed rule under 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 made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment.

A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. This proposed rule involves the establishment of a security zone and water activities including fireworks displays, swim events, and other marine events. This rule may be categorically excluded, under figure 2–1, paragraphs (1) and (34) (g) & (h) of the instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects

33 CFR Part 100

Marine safety, Navigation (water), Reporting and recording requirements, Waterways.

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 proposes to amend 33 CFR parts 100 and 165 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

2. Add a new § 100.100 to read as follows:

§ 100.100 Special Local Regulations; Regattas and Boat Races in the Coast Guard Sector Long Island Sound Captain of the Port Zone.

The following regulations apply to the marine events listed in the TABLE to § 100.100. These regulations will be enforced for the duration of each event, on or about the dates indicated. Annual notice of the exact dates and times of the effective period of the regulations with respect to each event, the geographical area, and details concerning the nature of the event and the number of participants and type(s) of vessels involved will be published in a Local Notices to Mariners and broadcast over VHF. First Coast Guard District Local Notice to Mariners can be found at: *http://www.navcen.uscg.gov/.*

Although listed in the Code of Federal Regulations, sponsors of events listed in TABLE to § 100.100 are still required to submit marine event applications in accordance with 33 CFR 100.15.

(a) Definitions. The following definitions apply to this section:

(1) Designated Representative. A ''designated representative'' is any Coast Guard commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the Captain of the Port, Sector Long Island Sound (COTP), to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(2) Official Patrol Vessels. Official patrol vessels may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP.

(3) Spectators. All persons and vessels not registered with the event sponsor as participants or official patrol vessels.

(b) Vessel operators desiring to enter or operate within the regulated areas shall contact the COTP or the designated representative via VHF channel 16.

(c) Vessels may not transit the regulated areas without the COTP or designated representative approval. Vessels permitted to transit must operate at a no wake speed, in a manner which will not endanger participants or other crafts in the event.

(d) Spectators or other vessels shall not anchor, block, loiter, or impede the transit of event participants or official patrol vessels in the regulated areas during the effective dates and times, or dates and times as modified through the Local Notice to Mariners, unless authorized by COTP or designated representative.

(e) The COTP or designated representative may control the movement of all vessels in the regulated area. When hailed or signaled by an official patrol vessel, a vessel shall come to an immediate stop and comply with the lawful directions issued. Failure to comply with a lawful direction may result in expulsion from the area, citation for failure to comply, or both.

(f) The COTP or designated representative may delay or terminate any marine event in this subpart at any time it is deemed necessary to ensure the safety of life or property.

(g) For all power boat races listed, vessels not participating in this event, swimmers, and personal watercraft of any nature are prohibited from entering or moving within the regulated area unless authorized by the COTP or designated representative. Vessels within the regulated area must be at anchor within a designated spectator area or moored to a waterfront facility in a way that will not interfere with the progress of the event.

TABLE TO § 100.100

1.1 Harvard-Yale Regatta, Thames River, New London, CT.	• Event type: Boat Race. • Date: May or June. • Location: All waters of the Thames River at New London, Connecticut, from the Penn Central Draw Bridge to Bartlett Cove. • Additional stipulations: Spectator vessels must be at anchor within a designated spectator area or moored to a waterfront facility within the regulated area in such a way that they shall not interfere with the progress of the event at least 30 minutes prior to the start of the races. They must remain moored or at anchor until the men's varsity have passed their positions. At that time, spectator vessels located south of the Harvard Boathouse may proceed downriver at a reasonable speed. Vessels situated between the Harvard Boathouse and the finish line must remain stationary until both crews return safely to their boathouses. If for any reason the men's varsity crew race is postponed, spectator vessels will remain in position until notified by Coast Guard or regatta patrol personnel. The last 1000 feet of the race course near the finish line will be delineated by four temporary white buoys provided by the sponsor. All spectator craft shall remain behind these buoys during the event. Spectator craft shall not anchor: To the west of the race course, between Scotch Cap and Bartlett Point Light, or within the race course boundaries or in such a manner that would allow their vessel to drift or swing into the race course. During the effective period all vessels shall proceed at a speed not to exceed six knots in the regulated area. Spectator vessels shall not follow the crews during the races. Swimming is prohibited in the vicinity of the race course during the races. A vessel operating in the vicinity of the Submarine Base may not cause waves which result in damage to submarines or other vessels in the floating drydocks.
1.2 Great Connecticut River Raft Race, Middletown, CT.	• Event type: Boat Race. • Date: Last Saturday in July or the first Saturday in August from 10 a.m. to 2 p.m. • Location: All waters of the Connecticut River between Dart Island (Marker no. 73) and Portland Shoals (Marker no. 92), Middletown, CT.
1.3 Head of the Connecticut Regatta, Connecticut River, CT.	• Event type: Boat Race. • Date: The second Saturday of October or as published in the Local Notice to Mariners. • Location: All waters of the Connecticut River between the southern tip of Gildersleeve Island and Light Number 87. • Additional stipulations: Vessels less than 20 meters in length will be allowed to transit the regulated area only under escort and at the discretion of the Coast Guard patrol commander. Vessels over 20 meters in length will be allowed to transit the regulated area, under escort, from 12:30 p.m. to 1:45 p.m. or as directed by the Coast Guard patrol commander. All transiting vessels shall operate at "No Wake" speed or five knots, whichever is slower. Southbound vessels awaiting escort through the regulated area will wait in the vicinity of the southern tip of Gildersleeve Island. Northbound vessels awaiting escort will wait at Light Number 87.
1.4 Riverfront Regatta, Hartford, CT	• Event type: Regatta. • Date: The first Sunday of October, from 8:30 a.m. to 4:30 p.m. • Location: All water of the Connecticut River, Hartford, CT, between the Putnum Bridge 41°42.87′ N 072°38.43′ W and the Riverside Boat House 41°46.42′ N, 072°39.83′ W (NAD 83).
1.5 Patchogue Grand Prix, Patchogue, NY	• Event type: Boat Race. • Date: The last weekend of August Friday, Saturday and Sunday, 11 a.m. until 5 p.m. • Location: All water of the Great South Bay, off Shorefront Park, Patchogue, NY from approximate position: Beginning at a point off Sand Spit Park, Patchogue, NY at position 40°44′45″ N, 073°00′51″ W then running south to a point in Great South Bay at position 40°43′46″N, 073°00′51″ W then running south east to position 40°43′41″ N, 073°00′20″ W then running north east to position 40°43′54″ N, 072°58′46″ W then east to position 40°43′58″ N, 072°57′32″ W then east to position 40°43′57″ N, 072°56′49″ W then north to position 40°44′18″ N, 072°56′49″ W then west to position 40°44′18″ N, 072°57′32″ W then north west to position 40°44′30″ N, 072°58′32″ W then north west to position 40°44′33″ N, 072°59′12″ W then north west to position 40°44′41″ N, 072°59′51″ W then north west to position 40°44′46″ N, 073°00′04″ W and then closing the zone at position 40°44′45″ N, 073°00′51″ W (NAD 83).
1.6 Riverfront U.S. Title series Powerboat Race, Hartford, CT.	• Event type: Boat Race. • Date: Labor Day weekend, 10 a.m. until 6 p.m. Friday and Saturday and 12:01 p.m. until 6 p.m. on Sunday.

TABLE TO § 100.100—Continued

	• Location: All water of the Connecticut River, Hartford, CT, between the Founders Bridge on the North approximate position 41° 45′53.47″ N, 072°39′55.77″ W and 41° 45′37.39″ N, 072°39′47.49″ W (NAD 83) to the South.

3. Remove the following entries in the ''Fireworks Display Table'' in § 100.114 (along with the associated ''Connecticut'' titles) as follows: 6.2, 7.1, 7.2, 7.4, 7.5, 7.10, 7.11, 7.29, 7.30, 7.31, 7.32, 7.33, 7.35, 7.36, 7.37, 7.39, 7.40, 8.1, 8.3, 8.4, 8.6, 9.3, 9.5, 9.6, 12.4.

4. Remove §§ 100.101, 100.102, 100.105, 100.106, 100.121, 100.122, 100.124.

PART 165—REGULATED NAVIGATION AREA AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapters 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; Department of Homeland Security Delegation No. 0170.1.

6. Remove § 165.140, 165.152, 165.155, 165.158, 165.159.

7. Revise § 165.151 to read as follows:

§ 165.151 Safety Zones; Fireworks Displays, Airshows and Swim Events in the Captain of the Port Long Island Sound Zone.

(a) Regulations.

The general regulations contained in 33 CFR 165.23 as well as the following regulations apply to the fireworks displays, air shows, and swim events listed in TABLES 1 and 2 to § 165.151.

These regulations will be enforced for the duration of each event. Notifications of exact dates and times of the enforcement period will be made to the local maritime community through the Local Notice to Mariners and Broadcast Notice to Mariners or through a Notice of Enforcement in the **Federal Register**. Mariners should consult the **Federal Register** or their Local Notice to Mariners to remain apprised of schedule or event changes. First Coast Guard District Local Notice to Mariners can be found at *http://www.navcen.uscg.gov/.*

Although listed in the Code of Federal Regulations, sponsors of events listed in TABLES 1 and 2 to § 165.151 are still required to submit marine event applications in accordance with 33 CFR 100.15.

(b) Definitions. The following definitions apply to this section:

(1) Designated Representative. A ''designated representative'' is any Coast Guard commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the Captain of the Port, Sector Long Island Sound (COTP), to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(2) Official Patrol Vessels. Official patrol vessels may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP.

(3) Spectators. All persons and vessels not registered with the event sponsor as participants or official patrol vessels.

(b) Vessel operators desiring to enter or operate within the regulated areas should contact the COTP or the designated representative via VHF channel 16 to obtain permission to do so.

(c) Spectators or other vessels shall not anchor, block, loiter, or impede the transit of event participants or official patrol vessels in the regulated areas during the effective dates and times, or dates and times as modified through the Local Notice to Mariners, unless authorized by COTP or designated representative.

(d) Upon being hailed by a U.S. Coast Guard vessel or the designated representative, by siren, radio, flashing light or other means, the operator of the vessel shall proceed as directed. Failure to comply with a lawful direction may result in expulsion from the area, citation for failure to comply, or both.

(e) The COTP or designated representative may delay or terminate any marine event in this subpart at any time it is deemed necessary to ensure the safety of life or property.

(f) The regulated area for all fireworks displays listed in TABLE 1 to § 165.151 is that area of navigable waters within a 1000 foot radius of the launch platform or launch site for each fireworks display, unless otherwise noted in TABLE 1 to § 165.151 or modified in USCG First District Local Notice to Mariners at: *http://www.navcen.uscg.gov/.*

(g) The regulated area for all air shows is the entire geographic area described as the location for that show unless otherwise noted in TABLE 1 to § 165.151 or modified in USCG First District Local Notice to Mariners at: *http://www.navcen.uscg.gov/.*

(h) Fireworks barges used in these locations will also have a sign on their port and starboard side labeled ''FIREWORKS—STAY AWAY.'' This sign will consist of 10 inch high by 1.5 inch wide red lettering on a white background. Shore sites used in these locations will display a sign labeled ''FIREWORKS—STAY AWAY'' with the same dimensions. These zones will be enforced from 8:30 p.m. to 10:30 p.m. each day a barge with a ''FIREWORKS—STAY AWAY'' sign on the port and starboard side is on-scene or a ''FIREWORKS—STAY AWAY'' sign is posted in a location listed in TABLE 1 to § 165.151.

(i) For all swim events listed in TABLE 2 to § 165.151, vessels not associated with the event shall maintain a separation of at least 100 yards from the participants.

TABLE 1—TO § 165.151

5—May	
5.1 Jones Beach Air Show	• Location: Waters of Atlantic Ocean off of Jones Beach State Park, Wantagh, NY. In approximate positions 40°35′06″ N, 073°32′37″ W, then running east along the shoreline of Jones Beach State Park to approximate position 40°35′49″ N, 073°28′47″ W; then running south to a position in the Atlantic Ocean off of Jones Beach at approximate position 40°35′05″ N, 073°28′34″ W; then running West to approximate position 40°34′23″ N, 073°32′23″ W; then running North to the point of origin. (NAD 83).

TABLE 1—TO § 165.151—Continued

6—June	
6.1 Barnum Festival Fireworks.	• Date: last weekend in June. • Rain Date: following day. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters of Bridgeport Harbor, Bridgeport, CT in approximate position 41°9′04″ N, 073°12′49″ W (NAD 83).
6.2 Town of Branford Fireworks.	• Location: Waters of Branford Harbor, Branford, CT in approximate position, 41°15′30″ N, 072°49′22″ W (NAD 83).
6.3 Vietnam Veterans/ Town of East Haven Fireworks.	• Location: Waters off Cosey Beach, East Haven, CT in approximate position, 41°14′19″ N, 072°52′9.8″ W (NAD 83).
7—July	
7.1 Point O'Woods Fire Company Summer Fireworks.	• Location: Waters of the Great South Bay, Point O'Woods, NY in approximate position 40°39′18.57″ N, 073°08′5.73″ W (NAD 83).
7.2 Cancer Center for Kids Fireworks.	• Location: Waters off of Bayville, NY in approximate position 40°54′38.20″ N, 073°34′56.88″ W (NAD 83).
7.3 City of Westbrook, CT July Celebration Fireworks.	• Location: Waters of Westbrook Harbor, Westbrook, CT in approximate position, 41°16′10.50″ N, 072°26′14″ W (NAD 83).
7.4 Norwalk Fireworks.	• Location: Waters off Calf Pasture Beach, Norwalk, CT in approximate position, 41°04′50″ N, 073°23′22″ W (NAD 83).
7.5 Lawrence Beach Club Fireworks.	• Location: Waters of the Atlantic Ocean off Lawrence Beach Club, Atlantic Beach, NY in approximate position 40°34′42.65″ N, 073°42′56.02″ W (NAD 83).
7.6 Sag Harbor Fireworks	• Location: Waters of Sag Harbor Bay off Havens Beach, Sag Harbor, NY in approximate position 41°00′26″ N, 072°17′9″ W (NAD 83).
7.7 South Hampton fresh Air Home Fireworks.	• Location: Waters of Shinnecock Bay, Southampton, NY in approximate positions, 40°51′48″ N, 072°26′30″ W (NAD 83).
7.8 Westport Police Athletic league Fireworks.	• Location: Waters off Compo Beach, Westport, CT in approximate position, 41°06′15″ N, 073°20′57″ W (NAD 83).
7.9 City of Middletown Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters of the Connecticut River, Middletown Harbor, Middletown, CT in approximate position 41°33′44.47″ N, 072°38′37.88″ W (NAD 83).
7.10 City of New Haven Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters of New Haven Harbor, off Long Warf Park, New Haven, CT in approximate position 41°17′24″ N, 072°54′55.8″ W (NAD 83).
7.11 City of Norwich July Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters of the Thames River, Norwich, CT in approximate position, 41°31′16.835″ N, 072°04′43.327″ W (NAD 83).
7.12 City of Stamford Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters of Fisher's Westcott Cove, Stamford, CT in approximate position 41°02′09.56″ N, 073°30′57.76″ W (NAD 83).
7.13 City of West Haven Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters of New Haven Harbor, off Bradley Point, West Haven, CT in approximate position 41°15′07″ N, 072°57′26″ W (NAD 83).
7.14 CDM Chamber of Commerce Annual Music Fest Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters off of Cedar Beach Town Park, Mount Sinai, NY in approximate position 40°57′59.58″ N, 073°01′57.87″ W (NAD 83).
7.15 Davis Park Fireworks	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m.

TABLE 1—TO § 165.151—Continued

	• Location: Waters of the Great South Bay, Davis Park, NY in approximate position, 40°41′17″ N, 073°00′20″ W (NAD 83).
7.16 Fairfield Aerial Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters of Jennings Beach, Fairfield, CT in approximate position 41°08′22″ N, 073°14′02″ W (NAD 83).
7.17 Fund in the Sun Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters of the Great South Bay off The Pines, East Fire Island, NY in approximate position 40°40′07.43″ N, 073°04′13.88″ W. (NAD 83).
7.18 Hartford Riverfest Fireworks.	• Date: July 4, 2010. • Rain Date: July 5, 2010. • Time 9:00 p.m. to 10:30 p.m. • Location: Waters of the Connecticut River off Hartford, CT in approximate position 41°45′21″ N, 072°39′28″ W (NAD 83).
7.19 Independence Day Celebration Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters off of Umbrella Beach, Montauk, NY in approximate position 41°01′44″ N, 071°57′13″ W (NAD 83).
7.20 Jones Beach State Park Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters off of Jones Beach State Park, Wantagh, NY in approximate position 40°34′56.676″ N, 073°30′31.186″ W (NAD 83).
7.21 Madison Cultural Arts Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters of Long Island Sound off of, Madison, CT in approximate position 41°16′10″ N, 072°36′30″ W (NAD 83).
7.22 Mason's Island Yacht Club Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters of Fisher's Island Sound, Noank, CT in approximate position 41°19′30.61″ N, 071°57′48.22″ W (NAD 83).
7.23 Patchogue Chamber of Commerce Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters of the Great South Bay, Patchogue, NY in approximate position, 40°44′38″ N, 073°00′33″ W (NAD 83).
7.24 Riverfest Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters of the Connecticut River Hartford, CT in approximate positions, 41°45′39.93″ N, 072°39′49.14″ W (NAD 83).
7.25 Village of Asharoken Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters of Northport Bay, Asharoken, NY in approximate position, 41°55′54.04″ N, 073°21′27.97″ W (NAD 83).
7.26 Village of Port Jefferson Fourth of July Celebration Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters of Port Jefferson Harbor Port Jefferson, NY in approximate position 40°57′10.11″ N, 073°04′28.01″ W (NAD 83).
7.27 Village of Quoque Foundering Anniversary Fireworks.	• Date: July 4, 2010. • Rain date: July 5, 2010. • Time: 8:30 p.m. to 10:30 p.m.

TABLE 1—TO § 165.151—Continued

	• Location: Waters of Quantuck Bay, Quoque, NY in approximate position 40°48′42.99″ N, 072°37′20.20″ W (NAD 83).
7.28 City of Long Beach Fireworks.	• Location: Waters off Riverside Blvd, City of Long Beach, NY in approximate position 40°34′38.77″ N, 073°39′41.32″ W (NAD 83).
7.29 Great South Bay Music Festival Fireworks.	• Location: Waters of Great South Bay, off Bay Avenue, Patchogue, NY in approximate position 40°44′45″ N, 073°00′25″ W (NAD 83).
7.30 Mashantucket Pequot Fireworks.	• Location: Waters of the Thames River New London, CT in approximate positions Barge 1, 41°21′03.03″ N, 072°5′24.5″ W Barge 2, 41°20′51.75″ N, 072°5′18.90″ W (NAD 83).
7.31 Shelter Island Fireworks.	• Location: Waters of Gardiner Bay, Shelter Island, NY in approximate position 41°04′39.11″ N, 072°22′01.07″ W (NAD 83).
7.32 Thames River Fireworks.	• Location: Waters of the Thames River off the Electric Boat Company, Groton, CT in approximate position 41°20′38.75″ N, 072°05′12.22″ W (NAD 83).
7.33 Clam Shell Foundation Fireworks.	• Location: Waters of Three Mile Harbor, East Hampton, NY in approximate position 41°1′15.49″ N, 072°11′27.50″ W (NAD 83).
7.34 Town of North Hempstead Bar Beach Fireworks.	• Location: Waters of Hempstead Harbor, North Hempstead, NY in approximate position 40°49′54″ N, 073°39′14″ W (NAD 83).
7.35 Groton Long Point Yacht Club Fireworks.	• Location: Waters of Long Island Sound, Groton, CT in approximate position 41°18′05″ N, 072°02′08″ W (NAD 83).
8—August	
8.1 Pyro-FX Entertainment Group Fireworks.	• Location: Waters of the Connecticut River off Chester, CT in approximate position 41°24′40.76″ N, 072°25′32.65″ W (NAD 83).
8.2 Port Washington Sons of Italy Fireworks.	• Location: Waters of Hempstead Harbor off Bar Beach, North Hempstead, NY in approximate position 40°49′48.04″ N, 073°39′24.32″ W (NAD 83).
8.3 Village of Bellport Fireworks.	• Location: Waters of Bellport Bay, off Bellport Dock, Bellport, NY in approximate position 40°45′01.83″ N, 072°55′50.43″ W (NAD 83).
8.4 Taste of Italy Fireworks	• Location: Waters of Norwich Harbor, off Norwich marina, Norwich, CT in approximate position 41°31′17.72″ N, 072°04′43.41″ W (NAD 83).
8.5 Old Black Point Beach Association Fireworks.	• Location: Waters off Old Black Point Beach East Lyme, CT in approximate position, 41°17′34.9″ N, 072°12′55″ W (NAD 83).
8.6 Town of Babylon Fireworks.	• Location: Waters off of Cedar Beach Town Park, Babylon, NY in approximate position 40°37′53″ N, 073°20′12″ W (NAD 83).
9—September	
9.1 East Hampton Fire Department Fireworks.	• Location: Waters off Main Beach, East Hampton, NY in approximate position 40°56′40.28″ N, 072°11′21.26″ W (NAD 83).
9.2 Town of Islip Labor Day Fireworks.	• Location: Waters of Great South Bay off Bay Shore Marina, Islip, NY in approximate position 40°42′24″ N, 073°14′24″ W (NAD 83).
9.3 Village of Island Park Labor Day Celebration Fireworks.	• Location: Waters off Village of Island Park Fishing Pier, Village Beach, NY in approximate position 40°36′30.95″ N, 073°39′22.23″ W (NAD 83).

TABLE 2 TO § 165.151

1.1 Swim Across the Sound	• Location: Waters of Long Island Sound, Port Jefferson, NY to Captain's Cove Seaport, Bridgeport, CT. in approximate positions 40°58′11.71″ N, 073°05′51.12″ W, north-westerly to the finishing point at Captain's Cove Seaport 41°09′25.07″ N, 073°12′47.82″ W (NAD 83).
1.2 Huntington Bay Open Water Championships Swim.	• Location: Waters of Huntington Bay, NY. In approximate positions start/finish at approximate position 40°54′25.8″ N, 073°24′28.8″ W, East turn at approximate position 40°54′45″ N, 073°23′36.6″ W and a West turn at approximate position 40°54′31.2″ N, 073°25′21″ W. °09′25.07″ N, 073°12′47.82″ W (NAD 83).
1.3 Maggie Fischer Memorial Great South Bay Cross Bay Swim.	• Location: Waters of the Great South Bay, NY. Starting Point at the Fire Island Lighthouse Dock in approximate position 40°38′01″ N, 073°13′07″ W, northerly through approximate points 40°38′52″ N, 073°13′09″ W, 40°39′40″ N, 073°13′30″ W, 40°40′30″ N, 073°14′00″ W, and finishing at Gilbert Park, Brightwaters, NY at approximate position 40°42′25″ N, 073°14′52″ W (NAD 83).

8. Revise § 165.154 to read as follows:

§ 165.154 Safety and Security Zones; Captain of the Port Long Island Sound Zone Safety and Security Zones.

The following areas are designated safety and security zones:

(a) Security zones.

(1) Dominion Millstone Nuclear Power Plant, Waterford, CT.

(i) All navigable waters of Long Island Sound, from surface to bottom, North and Northeast of a line running from Bay Point, at approximate position 41°18′34.199″ N., 072°10′24.6″ W., to Millstone Point at approximate position 41°18′15″ N., 072°9′57.599″ W. (NAD 83).

(ii) All navigable waters of Long Island Sound, from surface to bottom, West of a line starting at 41°18′42″ N., 072°9′38.998″ W., running south to the Eastern most point of Fox Island at approximate position 41°18′24.112″ N., 072°9′39.729″ W. (NAD 83).

(2) Electric Boat Shipyard, Groton, CT.

(i) Location. All navigable waters of the Thames River, from surface to bottom, West of the Electric Boat Corporation Shipyard enclosed by a line beginning at a point on the shoreline at

41°20′16″ N., 72°04′47″ W.; then running West to 41°20′16″ N., 72°04′57″ W.; then running North to 41°20′26″ N., 72°04′57″ W.; then Northwest to 41°20′28.7″ N., 72°05′01.7″ W.; then North-Northwest to 41°20′53.3″ N., 72°05′04.8″ W.; then North-Northeast to 41°21′02.9″ N., 72°05′04.9″ W.; then East to a point on shore at 41°21′02.9″ N., 72°04′58.2″ W. (NAD 83).

(ii) Application. Sections 165.33(a), (e), (f) shall not apply to public vessels or to vessels owned by, under hire to, or performing work for the Electric Boat Division when operating in the security zone.

(3) Naval Submarine Base, Groton, CT. All navigable waters of the Thames River, from surface to bottom, West of the Groton Naval Submarine Base New London, enclosed by a line beginning at a point on the shoreline at 41°23′15.8″ N., 72°05′17.9″ W.; then to 41°23′15.8″ N., 72°05′22″ W.; then to 41°23′25.9″ N., 72°05′29.9″ W.; then to 41°23′33.8″ N., 72°05′34.7″ W.; then to 41°23′37.0″ N., 72°05′38.0″ W.; then to 41°23′41.0″ N., 72°05′40.3″ W.; then to 41°23′47.2″ N., 72°05′42.3″ W.; then to 41°23′53.8″ N., 72°05′43.7″ W.; then to 41°23′59.8″ N., 72°05′43.0″ W.; then to 41°24′12.4″ N., 72°05′43.2″ W.; then to a point on the shoreline at 41°24′14.4″ N., 72°05′38″ W.; then along the shoreline to the point of beginning (NAD 83).

(4) U.S. Coast Guard Academy, New London, CT.

(i) Location. All navigable waters of the Thames River, from surface to bottom, in a 500-yard radius from Jacobs Rock, approximate position 41°22.36′N., 072°05.66′W. (NAD 83).

(ii) Enforcement period. This rule will be enforced during visits by high ranking officials and times of heighted security threats.

(iii) Notification. The Captain of the Port will notify the maritime community of periods during which this security zone will be enforced via Notice of Enforcement, Local Notice to Mariners and Marine Safety Information Radio Broadcasts.

(5) U.S. Coast Guard Vessels, Long Island Sound COTP Zone. All navigable waters within a 100-yard radius of any anchored U.S. Coast Guard vessel. For the purposes of this section, U.S. Coast Guard vessels includes any commissioned vessel or small boat in the service of the regular U.S. Coast Guard and does not include Coast Guard Auxiliary vessels

(b) Safety zones.

(1) Coast Guard Station Fire Island, Long Island, NY. All navigable waters of Fire Island Inlet beginning at a point on shore at 40°37.523′ N., 073°15.685′ W.; then North to 40°37.593′ N., 073°15.719′ W.; then East to 40°37.612′ N., 073°15.664′ W.; then East to 40°37.630′ N., 073°15.610′ W.; then East to 40°37.641′ N., 073°15.558′ W.; then Southeast to 40°37.630′ N., 073°15.475′ W.; then Southeast to 40°37.625′ N., 073°15.369′ W.; then Southeast to 40°37.627′ N., 073°15.318′ W.; then Southeast to point on shore at 40°37.565′ N., 073°15.346′ W. (NAD 83).

(c) Regulations.

(1) The general regulations contained in § 165.23 and § 165.33 of this part apply. Entering into, remaining within or cause an article or thing to enter into or remain within these safety and security zones is prohibited unless authorized by the Captain of the Port or a designated representative.

(2) These safety and security zones are closed to all vessel traffic, except as may be permitted by the Captain of the Port or a designated representative. Vessel operators given permission to enter or operate in the security zones must comply with all directions given to them by the Captain of the Port or a designated representative.

(3) The ''designated representative'' is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port to act on his/her behalf. The on-scene representative may be on a Coast Guard vessel, a state or local law enforcement vessel, or other designated craft, or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation

(4) Vessel operators desiring to enter or operate within the security zones shall request permission to do so by contacting the Captain of the Port Sector Long Island Sound at 203–468–4401, or via VHF Channel 16.

Dated: May 6, 2011.

J.M. Vojvodich,

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

[FR Doc. 2011–15589 Filed 6–21–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0426]

RIN 1625–AA00

Safety Zone; Patuxent River, Patuxent River, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone during the ''NAS Patuxent River Air Expo '11'', which consists of aerial practices, performance demonstrations and air shows, to be held over certain waters of the Patuxent River adjacent to Patuxent River, Maryland from September 1, 2011 through September 4, 2011. This proposed rule is necessary to provide for the safety of life on navigable waters during the event. This action is intended to temporarily restrict vessel traffic in portions of the Patuxent River during the event.

DATES: Comments and related material must be received by the Coast Guard on or before July 22, 2011.

ADDRESSES: You may submit comments identified by docket number USCG–2011–0426 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 proposed rule, call or e-mail Mr. Ronald Houck, Sector Baltimore Waterways Management Division, Coast Guard; telephone 410–576–2674, e-mail *Ronald.L.Houck@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2011–0426), 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 (via *http://www.regulations.gov*) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone 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,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rule'' and insert ''USCG–2011–0426'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape 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 the rule based on your comments.

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,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2011–0426'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. 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. We have an agreement with the Department of Transportation to use the Docket Management Facility.

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).

Public meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the four methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

U.S. Naval Air Station Patuxent River, Maryland is planning to conduct the ''NAS Patuxent River Air Expo '11'' on September 3, 2011 and September 4, 2011. The public event will consist of military and civilian aircraft performing low-flying, high-speed precision maneuvers and aerial stunts over both the airfield at Naval Air Station Patuxent River and the waters of the Patuxent River. Federal Aviation Administration restrictions require that portions of the Blue Angels and aerobatic performance boxes take place over the waters of the Patuxent River. In addition to the air show dates on September 3, 2011 and September 4, 2011, military and civilian aircraft performing in the air show will conduct practice and demonstration maneuvers and stunts over both the airfield at Naval Air Station Patuxent River and specified waters of the Patuxent River on September 1, 2011 and September 2, 2011. To provide for the safety of participants, spectators, and transiting vessels, the Coast Guard proposes to temporarily restrict vessel traffic on specified waters of the Patuxent River in the vicinity of the air shows, practices and demonstrations, and during other scheduled activities related to the air show. To address safety concerns during the event, the Captain of the Port, Baltimore proposes to establish a safety zone upon certain waters of the Patuxent River.

Discussion of Proposed Rule

The Captain of the Port Baltimore is proposing to establish a temporary safety zone for certain waters of the lower Patuxent River, located adjacent to the shoreline at U.S. Naval Air Station Patuxent River, Patuxent River, Maryland. One area of the proposed zone is located between Fishing Point and the base of the break wall marking the entrance to the East Patuxent Basin at Naval Air Station Patuxent River, within an area bounded by a line connecting position latitude 38°17′39″ N, longitude 076°25′47″ W; thence to latitude 38°17′47″ N, longitude 076°26′00″ W; thence to latitude 38°18′09″ N, longitude 076°25′40″ W; thence to latitude 38°18′00″ N, longitude 076°25′25″ W. Another area of the proposed zone is located north of the West Patuxent Basin at Naval Air Station Patuxent River, within an area bounded by a line drawn from a position at latitude 38°18′04″ N, longitude 076°27′35″ W; to latitude 38°18′09″ N, longitude 076°27′33″ W; thence to latitude 38°17′51″ N, longitude 076°26′22″ W; thence to latitude 38°17′46″ N, longitude 076°26′23″ W; thence to point of origin. Vessels underway in the safety zone at the time this safety zone is implemented will be required to immediately proceed out of the zone. Entry into this zone will be prohibited unless authorized by the Captain of the Port Baltimore or his designated representative. U.S. Coast Guard vessels will be provided to enforce the safety zone. The Captain of the Port Baltimore will issue Broadcast Notices to Mariners to publicize the safety zone and notify the public of changes in the status of the zone. Such notices will continue until the event is complete.

Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. Although this safety zone restricts vessel traffic through the affected area, the effect of this regulation will not be significant due to the limited

size and duration that the regulated area will be in effect. In addition, notifications will be made to the maritime community via marine information broadcasts so mariners may adjust their plans accordingly.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule may affect the following entities, some of which might be small entities: The owners or operators of vessels intending to operate or transit through or within the safety zone during the enforcement period. The safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons. The safety zone is of limited size and duration. Smaller vessels not constrained by their draft, which are more likely to be small entities, may transit around the safety zone. Maritime advisories will be widely available to the maritime community before the effective period.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Mr. Ronald L. Houck, Coast Guard Sector Baltimore, Waterways Management Division, at telephone number 410–576–2674. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

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

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

Environment

We have analyzed this proposed rule under 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 made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated

under **ADDRESSES**. This proposed rule involves establishing a temporary safety zone. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 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, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add a temporary section, § 165.T05–0426 to read as follows:

§ 165–T05–0426 Safety Zone; Patuxent River, Patuxent River, MD.

(a) *Regulated area.* The following locations are regulated areas:

(1) All waters of the lower Patuxent River, near Patuxent River, Maryland, located between Fishing Point and the base of the break wall marking the entrance to the East Patuxent Basin at Naval Air Station Patuxent River, within an area bounded by a line connecting position latitude 38°17′39″ N, longitude 076°25′47″ W; thence to latitude 38°17′47″ N, longitude 076°26′00″ W; thence to latitude 38°18′09″ N, longitude 076°25′40″ W; thence to latitude 38°18′00″ N, longitude 076°25′25″ W, located along the shoreline at U.S. Naval Air Station Patuxent River, Maryland.

(2) All waters of the lower Patuxent River, near Patuxent River, Maryland, located north of the West Patuxent Basin at Naval Air Station Patuxent River, within an area bounded by a line drawn from a position at latitude 38°18′04″ N, longitude 076°27′35″ W; to latitude 38°18′09″ N, longitude 076°27′33″ W; thence to latitude 38°17′51″ N, longitude 076°26′22″ W; thence to latitude 38°17′46″ N, longitude 076°26′23″ W; thence to point of origin, located adjacent to the shoreline at U.S. Naval Air Station Patuxent River, Maryland. All coordinates reference Datum NAD 1983.

(b) *Definitions:* As used in this section: (1) *Captain of the Port Baltimore* means the Commander, U.S. Coast Guard Sector Baltimore, Maryland.

(2) *Designated representative* means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Baltimore to assist in enforcing the safety zone described in paragraph (a) of this section.

Regulations: (1) All persons are required to comply with the general regulations governing safety zones found in 33 CFR 165.23.

(2) Entry into or remaining in this zone is prohibited unless authorized by the Coast Guard Captain of the Port Baltimore. Vessels already at berth, mooring, or anchor at the time the safety zone is implemented do not have to depart the safety zone. All vessels underway within this safety zone at the time it is implemented are to depart the zone.

(3) Persons desiring to transit the area of the safety zone must first request authorization from the Captain of the Port Baltimore or his designated representative. To seek permission to transit the area, the Captain of the Port Baltimore and his designated representatives can be contacted at telephone number 410–576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). The Coast Guard vessels enforcing this section can be contacted on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). Upon being hailed by a U.S. Coast Guard vessel, or other Federal, State, or local agency vessel, by siren, radio, flashing lights, or other means, the operator of a vessel shall proceed as directed. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port Baltimore or his designated representative and proceed at the minimum speed necessary to maintain a safe course while within the zone.

(4) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State, and local agencies.

(d) *Enforcement periods:* This section will be enforced as follows; (1) During the air show practice from 8 a.m. until 6 p.m. on September 1, 2011.

(2) Air show practice and modified show from 9 a.m. until 6 p.m. on September 2, 2011.

(3) Twilight performance from 4:30 p.m. until 8:30 p.m. on September 2, 2011.

(4) Air show performances from 8 a.m. until 7 p.m. on September 3, 2011 and from 8 a.m. until 7 p.m. on September 4, 2011.

Dated: May 30, 2011.

Mark P. O'Malley,

Captain, U.S. Coast Guard, Captain of the Port Baltimore Maryland.

[FR Doc. 2011–15586 Filed 6–21–11; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 51

[EPA–R09–OAR–2011–0130, FRL–9320–5]

Approval and Promulgation of Air Quality Implementation Plans; State of Nevada; Regional Haze State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a revision to the Nevada State Implementation Plan (SIP) to implement the regional haze program for the first planning period through July 31, 2018. The Clean Air Act (CAA) requires states to prevent any future and remedy any existing man-made impairment of visibility in 156 national parks and wilderness areas designated as Class I areas. Regional haze is caused by emissions of air pollutants from numerous sources located over a broad geographic area. States must submit SIPs that assure reasonable progress toward the national goal of achieving natural visibility conditions in Class I areas.

DATES: Written comments must be received at the address below on or before July 22, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2011–0130 by one of the following methods:

1. *Federal Rulemaking portal*: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
2. *E-mail: Webb.Thomas@epa.gov.*
3. *Fax:* 415–947–3579 (Attention: Thomas Webb).
4. *Mail:* Thomas Webb, EPA Region 9, Planning Office, Air Division, 75 Hawthorne Street, San Francisco, California 94105.
5. *Hand Delivery or Courier:* Such deliveries are only accepted Monday through Friday, 8:30 a.m.–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–R09–OAR–2011–

0130. Our policy is that EPA will include all comments received in the public docket without change. EPA may make comments available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA, without going through *http://www.regulations.gov,* EPA will include your e-mail address as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available (*e.g.,* CBI or other information whose disclosure is restricted by statute). Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at the Planning Office of the Air Division, Air-2, EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105. EPA requests 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, 9–5:30 PST, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Thomas Webb, U.S. EPA, Region 9, Planning Office, Air Division, Air-2, 75 Hawthorne Street, San Francisco, CA 94105. Thomas Webb can be reached at telephone number (415) 947–4139 and via electronic mail at *webb.thomas@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our,'' is used, we mean the United States Environmental Protection Agency (EPA).

Table of Contents

I. State Submittals
II. Background
A. Description of Regional Haze
B. History of Regional Haze Regulations
C. Roles of Agencies in addressing Regional Haze
III. Requirements for Regional Haze SIPs
A. Regional Haze Rule
B. Determination of Baseline, Natural and Current Visibility Conditions
C. Determination of Reasonable Progress Goals (RPGs)
D. Best Available Retrofit Technology (BART)
E. Long-Term Strategy (LTS)
F. Coordination of the Regional Haze SIP and Reasonably Attributable Visibility Impairment
G. Monitoring Strategy
H. SIP Revisions and Progress Reports
I. Coordination with Federal Land Managers (FLMs)
IV. EPA's Analysis of Nevada's RH SIP
A. Affected Class I Areas
B. Visibility Conditions and Uniform Rate of Progress (URP)
1. Baseline and Natural Visibility Conditions
2. Uniform Rate of Progress Estimate
C. Nevada Emissions Inventories
1. Emissions Inventories for 2002 and 2018
2. Analysis of Statewide Emissions by Pollutant
3. Analysis of Natural versus Anthropogenic Emissions
D. Sources of Visibility Impairment
1. Sources of Visibility Impairment at Jarbidge
2. Nevada's Contributions to Visibility Impairment in Class I Areas Outside of the State
E. Determination of Best Available Retrofit Technology
1. Sources eligible for BART
2. Sources subject to BART
3. BART Determinations
a. Tracy Generating Station
b. Fort Churchill Generating Station
c. Reid Gardner Generating Station
d. Mohave Generating Station
4. EPA's Assessment
F. Determination of Reasonable Progress Goal
1. Visibility Projections for 2018
2. Establishing the Reasonable Progress Goal
3. Interstate Consultation
G. Long-Term Strategy
1. BART Controls
2. Ongoing Air Pollution Control Programs
3. Construction Activities
4. Source Retirement and Replacement Schedules
5. Smoke Management Programs
6. Other Measures supporting the LTS
7. Interstate Transport Requirements for Visibility
H. Monitoring Strategy
1. Coordination of RAVI with RHR
2. Additional Monitoring Sites
3. Using and Reporting Monitoring Data
4. Statewide Emissions Inventory
I. State and Federal Land Manager Coordination
J. Periodic SIP Revisions and 5-year Progress Reports
V. EPA's Proposed Action
VI. Statutory and Executive Order Reviews

I. State Submittals

The Nevada Division of Environmental Protection (NDEP) adopted and transmitted its ''Nevada Regional Haze State Implementation Plan'' (Nevada RH SIP) to EPA Region 9 in a letter dated November 18, 2009. EPA determined the plan complete by operation of law on May 18, 2010. The SIP was properly noticed by the State and available for public comment for 30 days prior to a public hearing held in Carson City, Nevada, on May 20, 2009. There was a separate public notice and hearing on the proposed Best Available Retrofit Technology (BART) controls for four stationary sources, which the State adopted on April 23, 2009. The State submitted to EPA additional documentation of public process and adoption of a more stringent emission limit for one of the BART sources on February 18, 2010. Nevada included in its SIP responses to written comments from EPA Region 9, the National Park Service, and a consortium of conservation organizations. As a result of the State's participation with 13 other states, Tribal nations and Federal agencies in the Western Regional Air Partnership (WRAP), Nevada's RH SIP reflects a consistent approach toward addressing regional visibility impairment at 116 Class I areas in the West.

II. Background

A. Description of Regional Haze

Regional haze is the impairment of visibility across a broad geographic area produced by numerous sources and activities that emit fine particles and their precursors, primarily sulfur dioxide (SO_2) and nitrogen oxide (NO_X), and in some cases, ammonia (NH_3) and volatile organic compounds (VOC). Fine particle precursors react in the atmosphere to form fine particulate matter ($PM_{2.5}$), primarily sulfates, nitrates, organic carbon, elemental carbon, and soil dust, which impair visibility by scattering and absorbing light. Visibility impairment reduces the clarity, color, and visible distance that one can see. $PM_{2.5}$ can also cause

serious health effects and mortality in humans and contributes to environmental effects such as acid deposition and eutrophication.

Data from existing visibility monitors, the ''Interagency Monitoring of Protected Visual Environments'' (IMPROVE) network, indicate that visibility impairment caused by air pollution occurs virtually all the time at most Federally protected national parks and wilderness areas, known as Class I areas. The average visual range in many Class I areas in the western United States is 100 to 150 kilometers, or about one-half to two-thirds of the visual range that would exist without man-made air pollution.[1] In most of the eastern Class I areas of the United States, the average visual range is less than 30 kilometers, or about one-fifth of the visual range that would exist under estimated natural conditions. 64 FR 35715 (July 1, 1999).

B. History of Regional Haze Regulations

In section 169(A)(1) of the 1977 Amendments to the CAA, Congress established as a national goal the ''prevention of any future, and the remedying of any existing, impairment of visibility in mandatory class I Federal areas which impairment results from man-made air pollution.'' Visibility was determined to be an important value in 156 mandatory Class I Federal areas[2] as listed in 40 CFR 81.400–437. In the first phase of visibility protection, EPA promulgated regulations on December 2, 1980, to address visibility impairment in Class I areas that is ''reasonably attributable'' to a single source or small group of sources, *i.e.,* ''reasonably attributable visibility impairment'' or RAVI. 45 FR 80084. EPA deferred action on regional haze that emanates from a variety of sources until monitoring, modeling and scientific knowledge about the relationship between pollutants and visibility impairment were improved.

Congress added section 169B to the CAA in 1990 to conduct scientific research on regional haze. This legislation established the Grand Canyon Visibility Transport Commission (GCVTC), which issued its report, ''Recommendations for Improving Western Vistas,'' on June 10, 1996. These recommendations informed the regulatory development of a regional haze program, and provided an option for certain western states to address visibility at 16 Class I areas on the Colorado Plateau under 40 CFR 51.309.

EPA promulgated a rule to address regional haze on July 1, 1999 known as the Regional Haze Rule (RHR) (64 FR 35713). The RHR revised the existing visibility regulations to include provisions addressing regional haze impairment and established a comprehensive visibility protection program for Class I areas. The requirements for regional haze, found at 40 CFR 51.308 and 51.309, are included in EPA's visibility protection regulations at 40 CFR 51.300–309. Some of the major elements of the RHR requirements are summarized in section III of this notice. The requirement to submit a regional haze plan revision applies to all 50 states, the District of Columbia, and the Virgin Islands. States were required to submit the first implementation plan addressing regional haze visibility impairment no later than December 17, 2007. 40 CFR 51.308(b). Since most states, including Nevada, did not submit SIPs prior to the deadline, EPA made a Finding of Failure to Submit that extended the deadline to January 15, 2011, for EPA to approve a SIP or publish a Federal Implementation Plan (FIP). 74 FR 2392 (January 15, 2009). EPA is publishing this proposal to meet this obligation.

C. Roles of Agencies in Addressing Regional Haze

Successful implementation of the regional haze program will require long-term coordination among states, Tribal governments and various Federal agencies. As noted above, pollution affecting the air quality in Class I areas can result from the transport of pollutants over long distances, even hundreds of kilometers. Therefore, states and Tribal nations need to develop coordinated strategies to take into account the effect of emissions from one jurisdiction on the air quality in another. To support a regional approach to the planning process, EPA founded five regional planning organizations (RPOs) to assist states and Tribes in addressing regional haze and related issues. The RPOs first evaluated technical information to better understand how emissions impact Class I areas across the country, and then pursued the development of regional strategies to reduce pollutants contributing to regional haze.

The Western Regional Air Partnership (WRAP), one of five RPOs nationally, is a voluntary partnership of State, Tribal, Federal, and local air agencies focusing on improving visibility at 116 Class I areas in the West. WRAP member states include: Alaska, Arizona, California, Colorado, Idaho, Montana, New Mexico, North Dakota, Oregon, South Dakota, Utah, Washington and Wyoming. WRAP Tribal members include Campo Band of Kumeyaay Indians, Confederated Salish and Kootenai Tribes, Cortina Indian Rancheria, Hopi Tribe, Hualapai Nation of the Grand Canyon, Native Village of Shungnak, Nez Perce Tribe, Northern Cheyenne Tribe, Pueblo of Acoma, Pueblo of San Felipe, and Shoshone-Bannock Tribes of Fort Hall. While Nevada is not a formal member of the WRAP, State representatives participated fully in the WRAP and relied on its technical services and products as the basis for its plan.

While EPA regulates visibility at Class I areas, Federal Land Managers (FLMs) from the National Park Service, Fish and Wildlife Service, and Forest Service have a special role in the program because they have primary jurisdiction over Class I areas. FLMs may submit comments and make recommendations on a state's plan, and states are required to coordinate and consult with FLMs on most major planning and implementation requirements.

III. Requirements for Regional Haze SIPs

A. Regional Haze Rule

Regional haze SIPs must establish a long-term strategy that ensures reasonable progress toward achieving natural visibility conditions in each Class I area affected by the state's emissions. For each Class I area within its boundaries, the state must establish a reasonable progress goal (RPG) for the first planning period that ends on July 31, 2018. The long-term strategy must include enforceable emission limits and other measures as necessary to achieve the RPG. State implementation plans must also give specific attention to certain stationary sources that were in existence on August 7, 1977, but were not in operation before August 7, 1962. These sources, where appropriate, are required to install Best Available Retrofit Technology (BART) controls to eliminate or reduce visibility

[1] Visual range is the greatest distance, in kilometers or miles, at which one can view a dark object against the sky.

[2] Areas designated as mandatory Class I Federal areas consist of national parks exceeding 6000 acres, wilderness areas and national memorial parks exceeding 5000 acres, and all international parks that were in existence on August 7, 1977. 42 U.S.C. 7472(a). In accordance with section 169A of the CAA, EPA, in consultation with the Department of Interior, promulgated a list of 156 areas where visibility is identified as an important value. 44 FR 69122 (November 30, 1979). Although states and Tribes may designate as Class I additional areas which they consider to have visibility as an important value, the requirements of the visibility program set forth in section 169A of the CAA apply only to ''mandatory Class I Federal areas.'' Each mandatory Class I Federal area is the responsibility of a ''Federal Land Manager.'' 42 U.S.C. 7602(i). When we use the term ''Class I area'' in this action, we mean a ''mandatory Class I Federal area.''

impairment. The specific regional haze SIP requirements are summarized below.

B. Determination of Baseline, Natural and Current Visibility Conditions

The RHR establishes the deciview (dv) as the principal metric for measuring visibility. This visibility metric expresses uniform changes in haziness in terms of common increments across the entire range of visibility conditions, from pristine to extremely hazy conditions. Visibility expressed in deciviews is determined by using air quality measurements to estimate light extinction and then transforming the value of light extinction to deciviews using a logarithmic function. The deciview is a more useful measure for tracking progress in improving visibility than light extinction because each deciview change is an equal incremental change in visibility as perceived by the human eye. Most people can detect a change in visibility at one deciview.[3]

The deciview is used to express reasonable progress goals; define visibility conditions; and track changes in visibility. To track changes in visibility at each of the 156 Class I areas covered by the visibility program (40 CFR 81.401–437), and as part of the process for determining reasonable progress, states must calculate the degree of existing visibility impairment at each Class I area and periodically review progress midway through each ten-year implementation period. To do this, the RHR requires states to determine the degree of impairment (in deciviews) for the average of the 20 percent least impaired (''best'') and 20 percent most impaired (''worst'') visibility days over a specified time period at each of their Class I areas. In addition, states must develop an estimate of natural visibility conditions for the purpose of comparing progress toward the national goal. Natural visibility is determined by estimating the natural concentrations of pollutants that cause visibility impairment and then calculating total light extinction based on those estimates. EPA has provided guidance to states regarding how to calculate baseline, natural and current visibility conditions in documents titled, EPA's *Guidance for Estimating Natural Visibility Conditions Under the Regional Haze Rule,* September 2003, (EPA–454/B–03–005 located at *http://www.epa.gov/ttncaaa1/t1/memoranda/rh_envcurhr_gd.pdf*), (hereinafter referred to as ''EPA's 2003 Natural Visibility Guidance''), and *Guidance for Tracking Progress Under the Regional Haze Rule* (EPA–454/B–03–004 September 2003 located at *http://www.epa.gov/ttncaaa1/t1/memoranda/rh_tpurhr_gd.pdf*), hereinafter referred to as ''EPA's 2003 Tracking Progress Guidance'').

For the first regional haze SIPS that were due by December 17, 2007, ''baseline visibility conditions'' were the starting points for assessing ''current'' visibility impairment. Baseline visibility conditions represent the degree of visibility impairment for the 20 percent least impaired days and 20 percent most impaired days for each calendar year from 2000 to 2004. Using monitoring data for 2000 through 2004, states are required to calculate the average degree of visibility impairment for each Class I area, based on the average of annual values over the five-year period. The comparison of initial baseline visibility conditions to natural visibility conditions indicates the amount of improvement necessary to attain natural visibility, while the future comparison of baseline conditions to the then current conditions will indicate the amount of progress. In general, the 2000–2004 baseline period is considered the time from which improvement in visibility is measured.

C. Determination of Reasonable Progress Goals

The vehicle for ensuring continuing progress towards achieving the natural visibility goal is the submission of a series of regional haze SIPs that establish two RPGs (*i.e.,* two distinct goals, one for the ''best'' and one for the ''worst'' days) for every Class I area for each (approximately) ten-year implementation period. The RHR does not mandate specific milestones or rates of progress, but instead calls for states to establish goals that provide for ''reasonable progress'' toward achieving natural (*i.e.,* ''background'') visibility conditions. In setting reasonable progress goals (RPGs), states must provide for an improvement in visibility for the most impaired days over the (approximately) ten-year period of the SIP, and ensure no degradation in visibility for the least impaired days over the same period.

States have significant discretion in establishing RPGs, but are required to consider the following factors established in section 169A of the CAA and in EPA's RHR at 40 CFR 51.308(d)(1)(i)(A): (1) The costs of compliance; (2) the time necessary for compliance; (3) the energy and non-air quality environmental impacts of compliance; and (4) the remaining useful life of any potentially affected sources. States must demonstrate in their SIPs how these factors are considered when selecting the RPGs for the best and worst days for each applicable Class I area. States have considerable flexibility in how they take these factors into consideration, as noted in EPA's *Guidance for Setting Reasonable Progress Goals under the Regional Haze Program,* July 1, 2007, memorandum from William L. Wehrum, Acting Assistant Administrator for Air and Radiation, to EPA Regional Administrators, EPA Regions 1–10 (pp. 4–2, 5–1) (''EPA's Reasonable Progress Guidance''). In setting the RPGs, states must also consider the rate of progress needed to reach natural visibility conditions by 2064 (referred to as the ''uniform rate of progress'' (URP) or the ''glide path'') and the emission reduction measures needed to achieve that rate of progress over the ten-year period of the SIP. Uniform progress towards achievement of natural conditions by the year 2064 represents a rate of progress that states are to use for analytical comparison to the amount of progress they expect to achieve. In setting RPGs, each state with one or more Class I areas (''Class I state'') must also consult with potentially ''contributing states,'' *i.e.,* other nearby states with emission sources that may be affecting visibility impairment at the Class I state's areas. 40 CFR 51.308(d)(1)(iv).

D. Best Available Retrofit Technology

Section 169A of the CAA directs states to evaluate the use of retrofit controls at certain larger, often uncontrolled, older stationary sources in order to address visibility impacts from these sources. Specifically, section 169A(b)(2)(A) of the CAA requires states to revise their SIPs to contain such measures as may be necessary to make reasonable progress towards the natural visibility goal, including a requirement that certain categories of existing major stationary sources[4] built between 1962 and 1977 procure, install, and operate the ''Best Available Retrofit Technology'' as determined by the state. Under the RHR, states are directed to conduct BART determinations for such ''BART-eligible'' sources that may be anticipated to cause or contribute to any visibility impairment in a Class I area. Rather than requiring source-specific BART controls, states also have the flexibility to adopt an emissions trading program or other alternative program as

[3] The preamble to the RHR provides additional details about the deciview. 64 FR 35714, 35725 (July 1, 1999).

[4] The set of ''major stationary sources'' potentially subject to BART is listed in CAA section 169A(g)(7).

long as the alternative provides greater reasonable progress towards improving visibility than BART.

EPA published on July 6, 2005, the *Guidelines for BART Determinations under the Regional Haze Rule* at Appendix Y to 40 CFR part 51 (hereinafter referred to as the ''BART Guidelines'') to assist states in determining which of their sources should be subject to the BART requirements and in determining appropriate emission limits for each applicable source. In making a BART determination for a fossil fuel-fired electric generating plant with a total generating capacity in excess of 750 megawatts, a state must use the approach set forth in the BART Guidelines. A state is encouraged, but not required, to follow the BART Guidelines in making BART determinations for other types of sources.

States must address all visibility-impairing pollutants emitted by a source in the BART determination process. The most significant visibility impairing pollutants are SO_2, NO_X and PM. EPA has indicated that states should use their best judgment in determining whether VOC or NH_3 compounds impair visibility in Class I areas.

Under the BART Guidelines, states may select an exemption threshold value for their BART modeling, below which a BART-eligible source would not be expected to cause or contribute to visibility impairment in any Class I area. The state must document this exemption threshold value in the SIP and must state the basis for its selection of that value. Any source with emissions that model above the threshold value would be subject to a BART determination review. The BART Guidelines acknowledge varying circumstances affecting different Class I areas. States should consider the number of emission sources affecting the Class I areas at issue and the magnitude of the individual sources' impacts. An exemption threshold set by the state should not be higher than 0.5 deciview.

In their SIPs, states must identify potential BART sources, described in the RHR as ''BART-eligible sources,'' and document their BART control determination analyses. In making BART determinations, section 169A(g)(2) of the CAA requires that states consider the following factors: (1) The costs of compliance; (2) the energy and non-air quality environmental impacts of compliance; (3) any existing pollution control technology in use at the source; (4) the remaining useful life of the source; and, (5) the degree of improvement in visibility which may reasonably be anticipated to result from the use of such technology. States are free to determine the weight and significance assigned to each factor.

A regional haze SIP must include source-specific BART emission limits and compliance schedules for each source subject to BART. Once a state has made its BART determination, the BART controls must be installed and in operation as expeditiously as practicable, but no later than five years after the date EPA approves the regional haze SIP. CAA section 169(g)(4). 40 CFR 51.308(e)(1)(iv). In addition to what is required by the RHR, general SIP requirements mandate that the SIP must also include all regulatory requirements related to monitoring, recordkeeping and reporting for the BART controls on the source. States have the flexibility to choose the type of control measures they will use to meet the requirements of BART.

E. Long-Term Strategy

Consistent with the requirement in section 169A(b) of the CAA that states include in their regional haze SIP a ten- to fifteen-year strategy for making reasonable progress, section 51.308(d)(3) of the RHR requires that states include a long-term strategy (LTS) in their regional haze SIPs. The LTS is the compilation of all control measures a state will use during the implementation period of the specific SIP submittal to meet applicable RPGs. The LTS must include ''enforceable emissions limitations, compliance schedules, and other measures needed to achieve the reasonable progress goals'' for all Class I areas within and affected by emissions from the state. 40 CFR 51.308(d)(3).

When a state's emissions are reasonably anticipated to cause or contribute to visibility impairment in a Class I area located in another state, the RHR requires the impacted state to coordinate with contributing states to develop coordinated emissions management strategies. 40 CFR 51.308(d)(3)(i). In such cases, the contributing state must demonstrate that it has included in its SIP, all measures necessary to obtain its share of the emission reductions needed to meet the RPGs for the Class I area. The RPOs have provided forums for significant interstate consultation, but additional consultation between states may be required to sufficiently address interstate visibility issues (*e.g.,* where two states belong to different RPOs).

States should consider all types of anthropogenic sources of visibility impairment in developing their LTS, including stationary, minor, mobile, and area sources. At a minimum, states must describe how each of the following seven factors listed below are taken into account in developing their LTS: (1) Emission reductions due to ongoing air pollution control programs, including measures to address RAVI; (2) measures to mitigate the impacts of construction activities; (3) emissions limitations and schedules for compliance to achieve the RPG; (4) source retirement and replacement schedules; (5) smoke management techniques for agricultural and forestry management purposes including plans as currently exist within the state for these purposes; (6) enforceability of emissions limitations and control measures; and, (7) the anticipated net effect on visibility due to projected changes in point, area, and mobile source emissions over the period addressed by the LTS. 40 CFR 51.308(d)(3)(v).

F. Coordination of the Regional Haze SIP and Reasonably Attributable Visibility Impairment

As part of the RHR, EPA revised 40 CFR 51.306(c) regarding the long-term strategy for RAVI to require that the RAVI plan must provide for a periodic review and SIP revision not less frequently than every three years until the date of submission of the state's first plan addressing regional haze visibility impairment, which was due December 17, 2007, in accordance with 40 CFR 51.308(b) and (c). On or before this date, the state must revise its plan to provide for review and revision of a coordinated LTS for addressing RAVI and regional haze, and the state must submit the first such coordinated LTS with its first regional haze SIP. Future coordinated LTSs, and periodic progress reports evaluating progress towards RPGs, must be submitted consistent with the schedule for SIP submission and periodic progress reports set forth in 40 CFR 51.308(f) and 51.308(g), respectively. The periodic review of a state's LTS must report on both regional haze and RAVI impairment and must be submitted to EPA as a SIP revision.

G. Monitoring Strategy

Section 51.308(d)(4) of the RHR requires a monitoring strategy for measuring, characterizing, and reporting on regional haze visibility impairment that is representative of all mandatory Class I areas within the state. The strategy must be coordinated with the monitoring strategy required in 40 CFR 51.305 for RAVI. Compliance with this requirement may be met through ''participation'' in the Interagency Monitoring of Protected Visual

Environments (IMPROVE) network, *i.e.,* review and use of monitoring data from the network. The monitoring strategy is due with the first regional haze SIP, and it must be reviewed every five years. The monitoring strategy must also provide for additional monitoring sites if the IMPROVE network is not sufficient to determine whether RPGs will be met. The SIP must also provide for the following:

- Procedures for using monitoring data and other information in a state with mandatory Class I areas to determine the contribution of emissions from within the state to regional haze visibility impairment at Class I areas both within and outside the state;
- Procedures for using monitoring data and other information in a state with no mandatory Class I areas to determine the contribution of emissions from within the state to regional haze visibility impairment at Class I areas in other states;
- Reporting of all visibility monitoring data to the Administrator at least annually for each Class I area in the state, and where possible, in electronic format;
- Developing a statewide inventory of emissions of pollutants that are reasonably anticipated to cause or contribute to visibility impairment in any Class I area. The inventory must include emissions for a baseline year, emissions for the most recent year for which data are available, and estimates of future projected emissions. A state must also make a commitment to update the inventory periodically; and,
- Other elements, including reporting, recordkeeping, and other measures necessary to assess and report on visibility.

H. SIP Revisions and Progress Reports

The RHR requires control strategies to cover an initial implementation period through 2018, with a comprehensive reassessment and revision of those strategies, as appropriate, every ten years thereafter. Periodic SIP revisions must meet the core requirements of section 51.308(d) with the exception of BART. The requirement to evaluate sources for BART applies only to the first regional haze SIP. Facilities subject to BART must continue to comply with the BART provisions of section 51.308(e), as noted above. Periodic SIP revisions will assure that the statutory requirement of reasonable progress will continue to be met.

Each state also is required to submit a report to EPA every five years that evaluates progress toward achieving the RPG for each Class I area within the state and outside the state if affected by emissions from within the state. 40 CFR 51.308(g). The first progress report is due five years from submittal of the initial regional haze SIP revision. At the same time a 5-year progress report is submitted, a state must determine the adequacy of its existing SIP to achieve the established goals for visibility improvement. 40 CFR 51.308(h). The RHR contains more detailed requirements associated with these parts of the Rule.

I. Coordination With Federal Land Managers

The RHR requires that states consult with Federal Land Managers (FLMs) before adopting and submitting their SIPs. 40 CFR 51.308(i). States must provide FLMs an opportunity for consultation, in person and at least sixty days prior to holding any public hearing on the SIP. This consultation must include the opportunity for the FLMs to discuss their assessment of impairment of visibility in any Class I area and to offer recommendations on the development of the RPGs and on the development and implementation of strategies to address visibility impairment. Furthermore, a state must include in its SIP a description of how it addressed any comments provided by the FLMs. Finally, a SIP must provide procedures for continuing consultation between the state and FLMs regarding the state's visibility protection program, including development and review of SIP revisions, five-year progress reports, and the implementation of other programs having the potential to contribute to impairment of visibility in Class I areas.

IV. EPA's Analysis of Nevada's RH SIP

A. Affected Class I Areas

Nevada has one Class I area, the Jarbidge Wilderness Area (hereinafter referred to as Jarbidge), located within the Humboldt National Forest in the northeastern corner of the State. NDEP identified 24 other Class I areas [5] located outside the State that may be affected by its emissions. These other Class I areas are in Arizona (5), California (11), Idaho (2), Oregon (3) and Utah (3). In Arizona, the Class I areas are Grand Canyon National Park (NP), Sycamore Canyon Wilderness Area (WA), Pine Mountain WA, Mazatal WA, and Sierra Ancha WA. In California, they are Desolation WA, Dome Land WA, Hoover WA, Joshua Tree NP, Kaiser WA, Lassen Volcanic NP, Lava Beds WA, San Gabriel WA, San Gorgonio WA, Sequoia NP, and Yosemite NP. In Idaho, the areas are Craters of the Moon WA and Sawtooth WA. In Oregon, the areas are Crater Lake NP, Hells Canyon WA and Eagle Cap WA. In Utah, the areas are Bryce Canyon NP, Capitol Reef NP and Zion NP. EPA is proposing to find that NDEP has identified all affected Class I areas within and outside the State that are potentially affected by its emissions.

B. Visibility Conditions and Uniform Rate of Progress

NDEP developed the visibility estimates in its RH SIP using air quality models and analytical tools provided by the WRAP. Based on EPA's review of the WRAP's technical analyses and products, we found that the models were used appropriately, and were consistent with EPA guidance in effect at the time of their use. The models used by the WRAP were state-of–the-science at the time the modeling was conducted, and model performance was adequate for the purposes that they were used.[6]

1. Baseline and Natural Visibility Conditions

Baseline visibility conditions represent the degree of visibility impairment for the 20 percent least impaired days and 20 percent most impaired days for each calendar year from 2000 to 2004. Using monitoring data for 2000 through 2004, states are required to calculate the average degree of visibility impairment for each Class I area, based on the average of annual values over the five-year period.

NDEP calculated that on the 20 percent worst days at Jarbidge, the baseline visibility condition is 12.07 dv and the natural visibility condition is 7.87 dv. The natural visibility condition represents the long-term national goal of no man-made impairment. Since a state must ensure visibility improvement on the worst days, a baseline of 12.07 dv and an endpoint of 7.87 dv are used to measure progress. On the 20 percent best days, the baseline visibility condition is 2.56 dv and the natural visibility condition is 1.14 dv. The baseline visibility condition on best

[5] These Class I areas were identified using Particle Source Apportionment Tracking (PSAT) modeling results for sulfate and nitrate extinction. Tables 4–3 and 4–4 in the Nevada Regional Haze SIP identify the rank and percentage of the total modeled concentration due to SO_2 emissions and NO_X emissions from sources in Nevada to the IMPROVE monitors representing Class I areas in the five adjacent states. Where a monitoring site is not located within a specific national park or wilderness area, the closest Class I area is listed.

[6] For our detailed review and discussion, please see ''Technical Support Document for Technical Products Prepared by the Western Regional Air Partnership in support of Western Regional Haze Plans'', Final, February 2011 (WRAP TSD).

days is a value that must be maintained in future years.

2. Uniform Rate of Progress Estimate

NDEP calculated the uniform rate of progress (URP) estimate for Jarbidge using the deciviews for the 2000–2004 baseline and natural background conditions on the 20 percent worst days. The URP is represented as a straight line between a Class I area's baseline value and natural conditions in 2064. 40 CFR Section 51.308(d)(1)(i)(B). This line is linear and assumes the same increment of progress every year for 60 years.

NDEP calculated the URP for Jarbidge in 2018 as 11.09 dv. (See Table 1). Given baseline conditions of 12.07 dv and an estimate of natural conditions of 7.87 dv, the overall visibility improvement necessary to reach the national goal is 4.20 dv. As the regional haze rule requires the URP to be calculated over a 60-year period from baseline to natural conditions (2004 to 2064), the URP is an average annual improvement of 0.07 dv (4.20 dv divided by 60 years). A uniform rate of progress in the first planning period (2004 to 2018) would result in an improvement of 0.98 dv (14 years times .07 dv). Therefore, the URP in 2018 for Jarbidge is 11.09 dv (12.07 dv minus 0.98 dv).

NDEP produced the following visibility estimates in deciviews for its one Class I area: baseline visibility conditions, uniform rate of progress estimate for 2018, and natural conditions estimate for 2064. We propose to find that these estimates are consistent with the requirements of the RHR, particularly the requirements at 40 CFR 51.308(d)(2)(i) and (iii).

TABLE 1—VISIBILITY CALCULATIONS FOR JARBIDGE

[In deciviews]

Class I area	2000–20004 Baseline Condition (20% worst days)	2018 Uniform rate of progress (20% worst days)	2018 Reduction needed (20% worst days)	2064 Natural condition (20% worst days)	2000–2004 Baseline condition (20% best days)
Jarbidge Wilderness Area	12.07	11.09	0.98	7.87	2.56

Source: Table 2–1, page 2–7, Nevada RH SIP.

C. Nevada's Emissions Inventories

1. Emissions Inventories for 2002 and 2018

The RHR requires a statewide emissions inventory of pollutants that are reasonably anticipated to cause or contribute to visibility impairment in any mandatory Class I area. 40 CFR 51.308(d)(4)(v). NDEP provides a statewide emissions inventory for 2002, representing the mid-point of the 2000–2004 baseline period, and a projected emissions inventory for 2018, the end of the first 10-year planning period. The 2018 inventory is based on visibility modeling conducted by the WRAP's Regional Modeling Center using the Community Multi-Scale Air Quality (CMAQ) model. The emissions inventories for 2002 and 2018 provide estimates of annual emissions for haze producing pollutants by source category as summarized by EPA in Tables 2 and 3 based on information in Chapter 3 of Nevada's RH SIP. The inventoried pollutants include sulfur oxides (SO_x), nitrogen oxides (NO_X), volatile organic compounds (VOCs), fine particulate matter under 2.5 microns ($PM_{2.5}$), coarse particulate matter under 10 microns (PM_{10}), ammonia (NH_3), primary organic aerosol (POA),[7] and elemental carbon (EC). The emissions are divided into six source categories: point, area, mobile on-road, mobile off-road, natural and other. Natural sources include natural fire, biogenic and windblown dust. Other includes oil and gas, road dust, fugitive dust and anthropogenic fire. EPA is proposing to find that the emission inventories in Nevada's RH SIP were calculated using approved EPA methods.

TABLE 2—SUMMARY OF 2000–2004 AVERAGE BASELINE EMISSIONS FOR NEVADA

[tons per year]

	SO_X	NO_X	VOC	$PM_{2.5}$	PM_{10}	NH3	POA	EC
Point	50,947	59,873	2,215	2,158	4,093	339	256	13
Area	13,037	5,728	28,592	830	897	8,009	687	96
Mobile On-Road	510	41,089	36,257	0	245	2,030	314	235
Mobile Off-Road	1,672	32,565	18,094	0	0	22	572	1,354
Natural	2,784	23,103	811,745	11,844	99,122	1,684	22,501	4,674
Other	28	117	199	6,138	56,786	8	405	37
Total	68,978	162,475	897,102	20,970	161,143	12,092	24,734	6,409
Percent	(5)	(12)	(66)	(1.5)	(12)	(1)	(2)	(0.5)

[7] Instead of using the category of Organic Carbon, Nevada used the POA primary organic aerosol that includes organic molecules or compounds that are directly emitted from the combustion of organic material. These organic compounds include organic carbon, hydrogen, oxygen as well as other organic atoms.

TABLE 3—SUMMARY OF 2018 EMISSIONS FOR NEVADA

[Tons per year]

	SO_X	NO_X	VOC	$PM_{2.5}$	PM_{10}	NH_3	POA	EC
Point	28,320	67,632	3,866	2,211	4,717	864	168	13
Area	14,280	7,418	53,014	1,150	1,012	8,535	776	115
Mobile On-Road	336	15,049	17,085	0	360	3,385	422	121
Mobile Off-Road	473	22,182	11,784	0	0	30	393	668
Natural	2,784	23,103	811,745	11,844	99,122	1,684	22,501	4,674
Other	30	114	213	8,928	83,076	5	561	47
Total	46,223	135,498	897,707	24,133	188,287	14,503	24,822	5,638
Percent	(3.5)	(10)	(67)	(2)	(14)	(1)	(2)	(0.5)

2. Analysis of Statewide Emissions by Pollutant

NDEP's analysis of each pollutant in its emissions inventory, as summarized below, informs the relationship between the State's emissions and visibility impairment at Jarbidge as well as Class I areas outside the State.

• *Sulfur Dioxide:* SO_2 emissions are mostly from coal combustion at electrical generation facilities, but smaller amounts are from natural gas combustion, mobile sources and wood combustion. In Nevada, SO_X emissions are predominantly from point sources (61 percent) and area sources (31 percent). Statewide emissions of SO_2 are projected to decrease 33 percent by 2018 as compared to the baseline due to planned BART controls on power plants and to reductions in mobile source emissions due to Federal diesel fuel standards. Comparing 2018 projections to the baseline, SO_X emissions from point sources decrease 44 percent; area sources increase 10 percent; off-road mobile decrease 72 percent; and on-road mobile decrease 34 percent.

• *Nitrogen Oxide:* NO_X is generated during any combustion process where nitrogen and oxygen from the atmosphere combine to form nitric oxide and to a lesser extent nitrogen dioxide. NO_X emissions are predominantly from point sources (50 percent) and mobile sources (27 percent). Statewide emissions of NO_X are expected to decrease by 17 percent by 2018, primarily due to an estimated 36,423 ton reduction in emissions from mobile sources due to new Federal vehicle emission standards. While NO_X from point sources is projected to increase by 13 percent, the 2018 emissions inventory data does not include NO_X reductions from the installation of BART controls in Nevada. The projected increase of 29 percent in area sources by 2018 is largely due to forecasted increases in activity from population growth.

• *Volatile Organic Compounds:* VOCs are gases emitted by a wide array of man-made products and sources, but in Nevada are mostly from living organisms (90 percent), a natural source categorized as a biogenic. VOCs impact visibility as emissions condense in the atmosphere to form an organic aerosol. Projected emissions of VOCs are not expected to change by 2018.

• *$PM_{2.5}$*: PM fine emissions are composed of fine particulates that can remain suspended in the atmosphere for long periods of time and travel long distances. In Nevada, these emissions are generated mostly by natural fires (49 percent) and area sources (37 percent) such as woodstoves. Statewide emissions of $PM_{2.5}$ are expected to increase by 15 percent by 2018. Most of the increase is associated with fugitive dust related to increases in population. Overall, $PM_{2.5}$ is a relatively small part of the visibility problem compared to other pollutants.

• *PM_{10}*: PM coarse emissions are larger particles that travel shorter distances, but still contribute to regional visibility impairment. In Nevada, PM coarse emissions are predominately due to windblown dust (50 percent) and fugitive dust (36 percent). PM_{10} emissions are expected to increase about 17 percent by 2018 due mostly to projected increases in road dust and fugitive dust linked to increases in population. Windblown dust is not projected to change by 2018, and remains the primary source category for these emissions.

• *Ammonia:* NH_3 emissions are from a variety of sources including wastewater treatment facilities, livestock operations, fertilizer applications and mobile sources. NH_3 emissions are predominantly from area sources (59 percent) and on-road mobile sources (23 percent). The 2018 projections indicate a net increase of 20 percent, mostly from on-road mobile sources due to projected increases in population, and by extension, vehicular traffic. While emission estimates for NH_3 are hard to quantify, these pollutants are important because they react with SO_2 and NO_X to form ammonium sulfate (SO_4) and ammonium nitrate (NO_3) particles that are very effective in impairing visibility.

• *Primary Organic Aerosol:* POA includes organic molecules or compounds directly emitted from the combustion of organic material. Natural fire emissions (91 percent) dominate this category of statewide emissions.

• *Elemental Carbon:* EC particulates are emitted as a primary aerosol from fossil fuel combustion (vehicles, boilers, and other industrial processes), wild fires and other types of burning. In Nevada, the primary source of EC emissions is natural fire (83 percent) followed by off-road mobile (12 percent). Total EC emissions are projected to decrease 12 percent by 2018, mostly from mobile source emissions reductions resulting from Federal regulations.

3. Analysis of Natural Versus Anthropogenic Emissions

NDEP distinguishes between natural and anthropogenic sources of statewide emissions to indicate the type and level of emissions within the State that are amenable to controls. Table 4 provides a summary of anthropogenic and natural emissions based on the 2018 emissions inventory. The last column provides the percentage change in total emissions from the average emissions baseline.

TABLE 4—NATURAL V. ANTHROPOGENIC SOURCES EMISSIONS SUMMARY IN 2018

[Tons per year]

	Anthropogenic		Natural		Total in 2018	Change from baseline (%)
	Tons/year	% of total	Tons/year	% of total		
SO_X	43,440	94	2,784	6	46,224	−33.0
NO_X	112,394	83	23,102	17	135,496	−16.6
EC	964	17	4,674	83	5,638	−12.0
$PM_{2.5}$	12,289	51	11,845	49	24,134	15.1
PM_{10}	89,165	47	99,122	53	188,287	16.8
NH_3	12,819	88	1,684	12	14,503	19.9
POA	2,321	9	22,501	91	24,822	0.4
VOC	85,962	10	811,745	90	897,707	0.1
Total	359,354	27	977,458	73	1,336,811	−1.3

Source: Table 3–6, page 3–14, Nevada RH SIP.

NDEP estimates that about 73 percent of its statewide emissions in 2018 are projected to come from natural sources (*i.e.,* natural fires, windblown dust and biogenics). Natural sources contribute most of the emissions of EC, POA and VOC, and about half the emissions of $PM_{2.5}$ and PM_{10}. While anthropogenic sources comprise only 27 percent of the projected inventory in 2018, these sources are important contributors of SO_X, NO_X and NH_3 as well as half of $PM_{2.5}$ and PM_{10}.

D. Sources of Visibility Impairment

NDEP used baseline monitoring data presented in Table 5 to analyze the contribution of pollutants to light extinction (*i.e.,* visibility impairment) on the worst days at Jarbidge. The pollutants causing the highest levels of light extinction are associated with the sources causing the most visibility impairment. The primary contributors to light extinction at Jarbidge are organic matter carbon (40 percent), coarse matter (22.3 percent), and sulfates (16.7 percent). Elevated levels of organic carbon and its seasonal pattern suggest these particles are from wildfires and biogenic sources. Two components of organic carbon, POA and VOCs, are each 90 percent from natural sources as listed above in the 2018 emissions inventory. While anthropogenic emissions contributing to organic carbon may include fossil fuels combustion and wood burning, these are not likely sources at Jarbidge, which is an isolated national park. Similarly, coarse matter, also known as PM_{10}, is due mostly to naturally occurring events of windblown dust and fugitive dust based on the 2018 emissions inventory. Ammonia sulfate (SO_4) is the third highest contributor to light extinction on the worst days (16.7 percent), and the one most closely associated with anthropogenic sources. Soil ($PM_{2.5}$) and elemental carbon (EC) are mostly from natural fire, and ammonia nitrates (NO_3) have only a minimal contribution to light extinction at Jarbidge. This analysis indicates that most of the light extinction at Jarbidge is due to natural sources.

TABLE 5—PERCENTAGE OF LIGHT EXTINCTION AT JARBIDGE

[Baseline Period [8]]

Year	SO_4	NO_3	OMC	EC	Soil	CM	Sea salt
20 Percent Worst Days							
2001	14.6	3.5	38.6	8.4	10.4	24.2	0.3
2002	11.5	5.6	48.4	6.5	10.9	17.1	0.0
2003	17.3	3.1	40.8	6.3	7.7	24.8	0.0
2004	23.6	5.7	32.4	5.0	9.7	23.0	0.7
Average	16.7	4.5	40.0	6.5	9.7	22.3	0.3

Source: Table 2–2, page 2–19, Nevada RH SIP.

1. Sources of Visibility Impairment at Jarbidge

NDEP relied on source apportionment modeling [9] conducted by the WRAP to determine the sources of sulfate and nitrate particles at Jarbidge since these pollutants are commonly associated with anthropogenic sources. The source apportionment modeling results for the WRAP region on the worst days at Jarbidge in 2018 indicate that the relative contribution of particulate sulfate concentrations is primarily from point sources and natural fires in Idaho, Oregon, Washington, Nevada and California (in descending order). If one expands the modeling domain to include all areas outside the WRAP region, the areas of greatest sulfate contribution are Outside Domain [10]

[8] While the baseline period is from 2000 to 2004, the monitoring data for 2000 at Jarbidge was invalid because it failed to meet EPA's data completeness criteria.

[9] The WRAP's Regional Modeling Center used the Particulate Matter Source Apportionment Technology (PSAT) algorithm in the Comprehensive Air Quality Model with Extensions (CAMx) to attribute particle species, particularly sulfate and nitrate, from specific source areas and source categories within the WRAP region. The PSAT algorithm applies nitrate-sulfate-ammonia chemistry to a system of tracers to track chemical transformation, transport and dissipation of emissions based on a 36 kilometer grid cell within a specified source area.

[10] Outside Domain represents the background concentrations of pollutants that enter the modeling domain from sources outside the United States as

(43.8 percent), Idaho (10.3 percent), Oregon (7.2 percent), and Pacific Offshore (6.9 percent). Based on this analysis, Nevada contributes a relatively small amount (less than 5 percent) of sulfate at Jarbidge, which primarily comes from outside the United States.

Source apportionment modeling indicates that the areas of greatest nitrate contribution in the WRAP region on the worst days at Jarbidge in 2018 is primarily from area and mobile sources in Idaho, and mobile sources in Utah and Nevada. Point sources in all three states are also significant contributors. Including all areas outside the WRAP region, Idaho is the largest source of nitrates on the worst days (30.3 percent), followed by Outside Domain (27.5 percent), Nevada (13.1 percent), and Utah (10.6 percent). This analysis indicates that Nevada contributes a small amount of nitrates at Jarbidge.

In summary, the analysis of light extinction indicates that organic carbon and coarse matter from natural sources account for most of the visibility impairment at Jarbidge. While sulfates are an important contributor to light extinction, the vast majority of sulfate particles are from outside of Nevada.

2. Nevada's Contributions to Visibility Impairment in Class I Areas Outside of the State

NDEP identified the rank and percentage of sulfate extinction and nitrate extinction due to Nevada's emissions at IMPROVE monitors in each of 24 Class I areas in the five adjacent states.[11] The results for the best and worst days in 2002 and 2018 indicate that Nevada is responsible for a very small part of visibility impairment in Class I areas in Arizona, California, Idaho, Oregon and Utah. The highest concentration of sulfate extinction from Nevada's emissions in 2018 on the best days is 7.2 percent at Sawtooth Wilderness Area in Idaho, and on the worst days is 5.6 percent at Zion National Park in Utah. For nitrate extinction in 2018, Nevada's highest contribution on the best days is 12.4 percent at Joshua Tree National Park in California, and on the worst days is 20 percent at Desolation Wilderness in California. The next highest contribution of nitrate extinction is significantly lower, 8.8 percent at Bryce Canyon National Park in Utah. The level of Nevada's contributions to other Class I areas, mostly well below 10 percent, indicate that the vast majority of sulfates and nitrates in other Class I areas are from sources outside of Nevada. In conclusion, NDEP relied on source apportionment modeling to determine the relative contributions of haze causing pollutants in Class I areas inside and outside Nevada. We found these analyses to be valid and technically correct. We propose to find that the State has met the requirements of CFR 51.308(d)(3)(iii) and (iv).

E. Determination of Best Available Retrofit Technology (BART)

Nevada is required to evaluate the use of BART controls at 26 types of major stationary sources[12] built between 1962 and 1977 that have the potential to emit 250 tons or more of any pollutant and may reasonably be anticipated to cause or contribute to any impairment of visibility in any Class I area. CAA Section 169A(b)(2)(A) and 40 CFR 51.308(e). The state must submit a list of all BART-eligible sources within the state, and a determination of BART controls, including emissions limitations and schedules of compliance, for those sources subject to BART. Each source subject to BART is required to install and operate BART as expeditiously as practicable, but not later than five years after EPA approval of the state's regional haze SIP revision. CAA Section 169(g)(4) and 40 CFR 51.308(e)(1)(iv).

1. Sources Eligible for BART

The first phase of the BART evaluation is to identify all the BART-eligible sources within a state's boundaries. NDEP identified fourteen units at seven facilities as eligible for BART controls as listed below in Table 6. The seven facilities are Nevada Energy's Tracy (Mustang, NV), Fort Churchill (Yerington, NV), Reid Gardner (Moapa, NV) and Sunrise (Las Vegas, NV) electrical generating stations; Southern California Edison's Mohave generating station (Laughlin, NV); Nevada Cement Company's Portland cement plant (Fernley, NV); and Chemical Lime Company's Portland cement plant (Apex, NV). Mustang, Yerington, Moapa and Fernley are in eastern Nevada. Las Vegas, Laughlin and Apex are in southern Nevada. A map locating BART sources in relation to Class I areas is provided as Figure 1, page 5–5, in Nevada's RH SIP.

TABLE 6—SOURCES ELIGIBLE FOR BART IN NEVADA

Source (location)	Unit	Source category	Date in operation	Facility potential to emit (tons per year)		
				NO_X	SO_2	PM_{10}
Tracy (Mustang)	Boiler 1 Boiler 2 Boiler 3	Electric Generating Station	1963 1965 1974	1,167	21	125
Fort Churchill (Yerington)	Boiler 1 Boiler 2	Electric Generating Station	1968 1971	2,221	9	41
Reid Gardner (Moapa)	Boiler 1 Boiler 2 Boiler 3	Electric Generating Station	1965 1968 1976	7,045	1,020	1,343
Sunrise (Las Vegas)	Boiler 1	Electric Generating Station	1964	851	1	13
Mohave (Laughlin)	Boiler 1 Boiler 2	Electric Generating Station	1969 1969	20,267	40,347	1,958

well as portions of Canada and Mexico that are included in the modeling domain.

[11] See Table 4.3 Nevada's Sulfate Extinction Contribution to Class I Areas Outside of Nevada (page 4–15) and Table 4.4 Nevada's Nitrate Extinction Contribution to Class I Areas Outside of Nevada (page 4–17).

[12] The set of ''major stationary sources'' potentially subject to BART is listed in CAA section 169A(g)(7).

TABLE 6—SOURCES ELIGIBLE FOR BART IN NEVADA—Continued

Source (location)	Unit	Source category	Date in operation	Facility potential to emit (tons per year)		
				NO_X	SO_2	PM_{10}
Nevada Cement Company (Fernley).	Kiln 1 Kiln 2	Portland Cement Plant	1963 1967–68	2,065	96	80
Chemical Lime Company (Apex).	Kiln 3	Portland Cement Plant	1968	1,121	178	241

Source: Table 5–1, page 5–3, Nevada RH SIP.

2. Sources Subject to BART

The second phase of the BART determination process is to identify those BART-eligible sources that one may reasonably anticipate to cause or contribute to visibility impairment at any Class I area. These subject-to-BART sources are required to analyze what control measures, if any, constitute BART for the applicable SO_2, NO_X and PM_{10} emissions. A state may exempt a BART-eligible source from further BART review if the source is not reasonably anticipated to cause or contribute to any visibility impairment at any Class I area. As described in EPA's BART Guidelines,[13] a state may chose to use dispersion modeling to estimate a source's contribution to visibility impairment, an approach which requires the State to establish a threshold for contribution. Nevada established a 0.5 deciview threshold for exempting BART-eligible sources based on the results of dispersion modeling.[14]

NDEP determined that four of the seven eligible facilities are subject to BART since these facilities contribute to visibility impairment higher than 0.5 deciviews in one or more Class I areas. Information on the four subject-to-BART facilities is listed below in Table 7.

TABLE 7—SOURCES SUBJECT TO BART IN NEVADA

[Based on data from 2001–2003]

Facility	Class I areas within 300 km	Distance to class I area (km)	Highest impact on class I area	Days impact exceeds 0.5 dv
Tracy	Desolation	81	1.20	47
	Mokelumne	101	0.88	32
	Hoover	142	0.52	11
	Yosemite	153	0.50	11
	Caribou	170	1.03	48
	Lassen Volcanic	175	0.94	44
	South Warner	189	0.99	62
	Lava Beds	286	0.74	25
Fort Churchill	Mokelumne	78	1.24	69
	Desolation	85	1.25	72
	Hoover	99	1.00	32
	Emigrant	100	0.68	25
	Yosemite	112	1.00	29
	Ansel Adams	132	0.70	28
	John Muir	169	0.56	24
	Caribou	226	0.77	34
	Lassen Volcanic	231	0.77	33
	South Warner	245	0.72	62
	Thousand Lakes	265	0.60	21
Reid Gardner	Grand Canyon	85	1.72	60
	Zion	148	0.83	38
	Joshua Tree	292	0.88	48
Mohave	Grand Canyon	110	4.61	498
	Joshua Tree	137	4.58	248
	Sycamore Canyon	223	1.51	111
	San Gorgonio	225	1.44	75
	San Jacinto	234	1.62	74
	Zion	262	2.58	270
	Pine Mountain	265	1.21	49
	Dome Land	268	1.97	72
	Mazatal	279	1.19	45

[13] EPA's Guidelines for BART Determinations under the Regional Haze Rule are at 40 CFR Part 51 Appendix Y or 70 FR 39104 (July 6, 2005). For information on setting the contribution threshold refer to 70 FR 39161 (July 6, 2005).

[14] WRAP's RMC used the CALPUFF modeling system to assess whether Nevada's eligible sources were subject to or exempt from BART by estimating impacts from a single source on each Class I area within 300 km of any BART-eligible facility. The highest modeled impact in the fourth column is the maximum annual 98th percentile delta deciview (8th highest value) of the three years analyzed.

TABLE 7—SOURCES SUBJECT TO BART IN NEVADA—Continued

[Based on data from 2001–2003]

Facility	Class I areas within 300 km	Distance to class I area (km)	Highest impact on class I area	Days impact exceeds 0.5 dv
	Aqua Tibia	286	1.15	54
	Cucamonga	287	1.38	51

Source: Table 5–2, page 5–6 Nevada RH SIP.

Nevada determined that three BART-eligible facilities are not required to evaluate control options because these facilities modeled below the visibility impairment threshold of 0.5 deciviews based on the 98th percentile deciview. These facilities are the Sunrise Generating Station, the Nevada Cement Company, and the Chemical Lime Company listed below in Table 8. The fourth BART-eligible facility, Mohave Generating Station, has ceased operating.[15] A summary of the WRAP's BART exemption modeling for these facilities is available at *http://ndep.nv.gov/baqp/planmodeling/rhaze.html*.

TABLE 8—SOURCES EXEMPT FROM BART IN NEVADA

Facility	Class I areas within 300 km	Distance to class I area (km)	Highest impact on class I area	Days impact exceeds 0.5 dv
Sunrise Generating Station	Grand Canyon	95	0.20	1
	Zion	207	0.11	0
	Joshua Tree	228	0.16	0
	Dome Land	237	0.08	0
	San Gorgonio	271	0.08	0
	John Muir	282	0.06	0
	Bryce Canyon	284	0.04	0
	Sequoia	288	0.04	0
	San Jacinto	290	0.06	0
	Sycamore Canyon	290	0.03	0
Nevada Cement Company	Desolation	101	0.27	3
	Mokelumne	115	0.31	3
	Emigrant	148	0.16	0
	Hoover	150	0.22	0
	Yosemite	161	0.22	0
	Caribou	185	0.48	6
	Ansel Adams	186	0.18	0
	Lassen Volcanic	191	0.46	6
	South Warner	224	0.49	7
	John Muir	224	0.14	0
	Thousand Lakes	254	0.26	4
	Kaiser	267	0.08	0
	Kings Canyon	294	0.11	0
	Lava Beds	294	0.22	0
Chemical Lime Company	Grand Canyon	89	0.05	0
	Zion	185	0.03	0
	Joshua Tree	254	0.04	0
	Dome Land	256	0.02	0
	Bryce Canyon	263	0.01	0
	John Muir	290	0.01	0
	Sycamore	292	0.01	0
	Sequoia	296	0.01	0
	San Gorgonio	297	0.02	0

Source: Table 5–3, page 5–7, Nevada RH SIP.

NDEP based its contribution threshold on four factors. First, 0.5 deciviews equates to the five percent extinction threshold for new sources under the Prevention of Significant Deterioration and New Source Review rules. Second, this value is consistent with the threshold selected by all other states in the West. Third, it represents the limit of perceptible change. Fourth, there was no clear rationale or justification for selecting a lower level. This explanation, however, is inadequate for adopting a 0.5 dv threshold to determine whether a BART source may

[15] The Mohave Generating Station has ceased all operations related to the generation of electricity from burning coal. NDEP approved Southern California Edison's request to terminate their Air Quality Operating Permit (No. AP4911–0774, FIN A0013) on April 9, 2010.

be reasonably anticipated to cause or contribute to any visibility impairment in a Class I area. Based on EPA's review of the BART-eligible sources, however, EPA is proposing to find that a 0.5 dv threshold is appropriate, given the specific facts in Nevada.

In the BART Guidelines, EPA recommended that States ''consider the number of BART sources affecting the Class I areas at issue and the magnitude of the individual sources' impacts. In general, a larger number of BART sources causing impacts in a Class I area may warrant a lower contribution threshold.'' 70 FR 39104, 39161 July 6, 2005. Since four of the sources are subject to BART, EPA focused its review on the modeled impacts of the three BART-exempt sources as listed in the fourth column of Table 8. Of those sources, Nevada Cement Company has estimated impacts of close to 0.5 dv at three of the fourteen potentially impacted Class I areas. Nevada Cement's highest modeled impacts are at Caribou WA (0.48 dv), Lassen Volcanic NP (0.46 dv) and South Warner WA (0.49 dv). Of the BART-eligible sources, only Tracy and Fort Churchill also impact visibility in these three Class I areas. NDEP found both Tracy and Fort Churchill to be subject to BART based on its threshold of 0.5 dv. Thus, only a small number of BART-eligible sources, two of which were found to be subject to BART, are impacting Caribou WA, Lassen Volcanic NP, and South Warner WA above or close to the threshold level of 0.5 dv. In comparison to Nevada Cement, Sunrise's highest impact is 0.20 dv and Chemical Lime's highest impact is 0.05, both on Grand Canyon NP. Of the other BART-subject sources impacting visibility at the Grand Canyon, Mohave has closed and Reid Gardner is subject to BART controls. Given the relatively limited impact on visibility from the three exempted sources, NDEP could have reasonably concluded that a 0.5 dv threshold was appropriate for identifying those BART-eligible sources with significant impacts on visibility in Class I areas. Based on our analysis, EPA is proposing to approve the 0.5 dv threshold adopted by Nevada in its Regional Haze SIP.

3. BART Determinations

NDEP completed BART determinations and set emission limits for the eligible units at the Tracy, Churchill, and Reid Gardner electrical generating stations in conformance with EPA's BART Guidelines. Control technologies or measures identified by NDEP as BART are required to be installed and operating on units at these three facilities by January 1, 2015, or no later than five years after approval of Nevada's RH SIP, whichever occurs sooner. The designated BART controls, emission limits, and compliance deadlines are enforceable through Nevada State regulation R190–08, adopted on April 23, 2009. Nevada Energy's BART reports and NDEP's BART determinations are available at *http://ndep.nv.gov/baqp/planmodeling/rhaze.html*. Nevada Energy is the owner and operator of Tracy, Fort Churchill and Reid Gardner. NDEP made its BART determinations based on the BART reports from Nevada Energy, additional economic analysis, and baseline emission scenarios for NO_X and SO_2 using emissions data from EPA's Acid Rain Program. Please refer to Chapter 5 of the Nevada RH SIP for further information.

a. Tracy Generating Station

Background: Tracy is a natural gas-fueled power plant complex with 12 generating units located about 17 miles east of Reno, Nevada. The plant consists of three BART-eligible steam boiler units completed in 1963, 1965 and 1974. These units have a generating capacity of about 251 megawatts (MW), of which unit 1 is 55 MW, unit 2 is 83 MW and unit 3 is 113 MW. The Title V permit allows burning pipeline quality natural gas (PNG) or blended residual fuel oil (No. 2 and No. 6 and non-PCB mineral oil). Nevada Energy, the owner, completed a BART analysis for Tracy that investigated technology alternatives and potential reductions in NO_X, SO_2 and PM_{10} emissions rates in a report dated October 2008. NDEP partially concurred with Nevada Energy's analysis of BART controls, but disagreed that installation of only low NO_X burners (LNB) for control of NO_X emissions at units 2 and 3 was BART. NDEP set lower NO_X emission limits at all three units than those requested by Nevada Energy. NDEP reviewed Nevada Energy's five-factor analysis for each unit at Tracy and determined that installation of LNB with flue gas recirculation (FGR) for units 1 and 2, as well as LNB with selective non-catalytic reduction (SNCR) for unit 3, meet the BART criteria. Associated first year costs range from $2,383 to $3,050/ton of NO_X removed. NDEP considered these values to be cost effective. Based on a review of Nevada Energy's economic analysis, NDEP concluded that the dollars per ton of NO_X removed for units 1 and 2 increased significantly for LNB with SNCR, rotating opposed fire air (ROFA) with Rotamix,[16] and selective catalytic reduction (SCR), with only slight improvements in visibility. For unit 2, although LNB with SNCR appears cost effective, that technology does not reduce the modeled average number of days above 0.5 deciviews at the Desolation Wilderness Area or Yosemite National Park. For unit 3, although the first year cost effectiveness for ROFA with Rotamix appears reasonable, the incremental cost effectiveness of ROFA with Rotamix is much higher than LNB with SNCR. It also does not reduce the modeled average number of days above 0.5 deciviews at Desolation Wilderness or Yosemite. Support documents for Nevada's BART determinations are at *http://ndep.nv.gov/baqp/planmodeling/rhaze.html.*

Regarding BART for SO_2, NDEP agreed with Nevada Energy's analysis to require Pipeline Quality Natural Gas (PNG) or low sulfur No. 2 fuel oil with an emission limit of 0.05 lb/MMBtu over a 24-hour averaging time for all three units. NDEP also agreed with Nevada Energy that BART for PM_{10} for all three units is PNG or low sulfur No. 2 fuel oil with an emission limit of 0.03 lb/MMBtu over a 3-hour average.

BART Controls: For units 1 and 2 at Tracy, EPA proposes to agree with NDEP's analysis that BART for NO_X is LNB with FGR and emission limits of 0.15 lb/MMBtu and 0.12 lb/MMBtu, respectively, based on a 12-month rolling average. For unit 3, EPA proposes to agree with NDEP's analysis that BART for NO_X is LNB with SNCR and an emission limit of 0.19 lb/MMBtu, based on a 12-month rolling average. EPA also proposes to approve NDEP's conclusion to eliminate the additional control options that Nevada Energy analyzed based on its finding those options had significantly higher incremental cost effectiveness and/or would not reduce the frequency of impaired visibility at Class I areas. EPA proposes to agree that for all units at Tracy, BART for SO_2 is PNG and/or No. 2 fuel oil with an emission limit of 0.05 lb/MMBtu, based on a 24-hour averaging period. For PM_{10}, EPA proposes to agree with NDEP's analysis that BART is also PNG and/or No. 2 fuel oil, but with an emission limit of 0.03 lb/MMBtu, based on a 3-hour averaging period for all units.

Visibility Improvement: Based on visibility modeling, emissions reductions due to the installation of BART controls at Tracy result in 82 less days every year with visibility impacts greater than 0.5 dv at fifteen Class 1 areas within 300 km of the facility. NDEP anticipates even greater visibility improvement from BART than modeled

[16] Rotamix is a technology for adding SNCR using ammonia or a urea-based reagent.

because the actual NO_X emission limits for BART (0.12–0.19 lb/MMBtu) are much lower than the emission rates (0.40 lb/MMBtu) used to model visibility improvement due to BART implementation.

b. Fort Churchill Generating Station

Background: Fort Churchill is a natural gas-fired power plant located in Yerington, Nevada, that uses steam boilers to drive turbine generators. The plant consists of two units, completed in 1968 and 1971, that are BART-eligible with a generating capacity of 113 megawatts each. The fuel currently used in units 1 and 2 is PNG or blended fuel oil (No. 6 residual oil and No. 2 distillate fuel oil). In its BART analysis, Nevada Energy investigated technology alternatives and identified potential reductions in NO_X, SO_2 and PM_{10} emissions rates. NDEP partially concurred with Nevada Energy's analysis of BART controls, but disagreed that installation of only LNB for control of NO_X emissions was BART, and disagreed with the associated NO_X emission limits. For unit 1, LNB with SNCR and ROFA with Rotamix appear cost effective in the first year costs, but have significantly higher incremental cost effectiveness than LNB with FGR. In addition, LNB with SNCR and ROFA with Rotamix do not show fewer modeled average number of days above 0.5 deciviews at Mokelumne Wilderness Area and Yosemite. For unit 2, LNB with SNCR and ROFA with Rotamix appear to be cost effective in the first year, but have significantly higher incremental cost effectiveness than LNB with FGR. Nevada Energy's modeling analysis shows that LNB with SNCR does not result in any fewer averaged number of days above 0.5 deciviews at Mokulumne and only one fewer averaged days above 0.5 delta deciviews at Yosemite.

Regarding BART for SO_2, NDEP agreed with Nevada Energy's analysis to require PNG or low sulfur No. 2 fuel oil with an emission limit of 0.05 lb/MMBtu over a 24-hour averaging time for all three units. NDEP also agreed with Nevada Energy that BART for PM_{10} for all three units is PNG or low sulfur No. 2 fuel oil with an emission limit of 0.03 lb/MMBtu over a 3-hour average.

BART Controls: For units 1 and 2 at Fort Churchill, EPA is proposing to approve NDEP's determination that BART for NO_X is LNB with FGR and emission limits of 0.20 lb/MMBtu and 0.16 lb/MMBtu, respectively, based on a 12-month rolling average. EPA proposes to approve NDEP's decision to eliminate the additional control options that Nevada Energy analyzed based on its finding those options had significantly higher incremental cost effectiveness or would not reduce the frequency of impaired visibility at Class I areas.

For SO_2, EPA proposes to agree with NDEP's analysis that BART is PNG and/or No. 2 fuel oil for all units with an emission limit of 0.05 lb/MMBtu, based on a 24-hour averaging period. For PM_{10}, EPA proposes to find that BART is also PNG and/or No. 2 fuel oil for all units, with an emission limit of 0.03 lb/MMBtu, based on a 3-hour averaging period.

Visibility Improvement: Based on visibility modeling, emission reductions due to the installation of BART controls at Fort Churchill result in 227 less days every year with visibility impacts greater than 0.5 dv at fourteen Class 1 areas within 300 km of the facility. NDEP anticipates even greater visibility improvement from BART than modeled because the actual NO_X emission limits for BART (0.12 and 0.16 lb/MMBtu) are much less than the emission rates (0.40 lb/MMBtu) used to model visibility improvement due to BART implementation. For Fort Churchill, the total annual NO_X emissions post-BART controls (963 tpy) are 53 percent of those modeled (2,181 tpy).

c. Reid Gardner Generating Station

Background: Reid Gardner is a coal-fueled, steam-electric generating plant with four operating units producing a total of 557 MW. Three of the units, built in 1965, 1968 and 1976 are BART-eligible. Each of these units produces about 100 MW with steam boilers that drive turbine-generators. The units are equipped with LNB and over-fire air (OFA) system, mechanical collectors for particulate control, wet scrubbers that use soda ash for SO_2 removal, as well as recently installed baghouses. NDEP's review of Nevada Energy's BART report for Reid Gardner resulted in NDEP agreeing only with the control technologies proposed as BART for SO_2 and PM_{10}. For the three BART units, NDEP concurs that BART for SO_2 is the existing wet soda ash FGD and BART for PM_{10} is the recently installed fabric filter baghouse. NDEP disagreed with Nevada Energy's conclusion on BART for NO_X, and on the proposed emission limits for NO_X, SO_2 and PM_{10}. NDEP later responded to comments from EPA, FLMs and other non-governmental organizations regarding its proposed BART SO_2 emission limit for Reid Gardner. After further evaluation of emission data that reflected compliance with existing controls at the facility, NDEP lowered the SO_2 emissions limit at Reid Gardner from 0.25 lb/MMBtu to 0.15 lb/MMBtu on all three units. The revised BART regulation was adopted by the Nevada Environmental Commission on February 11, 2009 and submitted to EPA as a revision to NDEP's RH SIP on February 18, 2010.

BART Controls: NDEP determined that for all units at Reid Gardner, BART controls for NO_X are rotating opposed fire air (ROFA) with Rotamix and emission limits of 0.20 lb/MMBtu for units 1 and 2, and 0.28 lb/MMBtu for unit 3, based on a 12-month rolling average. To evaluate the cost of compliance, NDEP analyzed the cost per year of the various control technologies compared to the tons of NO_X removed by each. NDEP determined that the additional cost per year for SCR technologies did not appear cost effective compared to the additional NO_X reduction for each unit. NDEP also evaluated the second BART factor, energy and non-air quality environmental impacts, for requiring SCR or SNCR rather than ROFA with Rotamix. NDEP determined that there were negative non-air quality environmental impacts with SCR and SNCR, including the salability and ultimate disposal of fly ash due to higher ammonia levels. Moreover, NDEP found that SCR and SNCR increased the potential for creating a visible stack plume. NDEP also was concerned about the transportation of ammonia to Reid Gardner increasing the likelihood of an accidental release. EPA is proposing to approve these BART determinations for NO_X based on NDEP's approach.

EPA proposes to agree that BART controls for SO_2 are wet soda ash flue gas desulfurization on all units with an emission limit of 0.15 lb/MMBtu, based on a 24-hour averaging period. We also propose to agree that for PM_{10}, BART controls are fabric filter baghouses on all units with an emission limit of 0.015 lb/MMBtu, based on 3-hour averaging period.

Visibility Improvement: Based on visibility modeling, emission reductions due to the installation of BART controls at Reid Gardner result in five less days with visibility impacts greater than 0.5 dv at five Class I areas within 300 kilometers of the facility. NDEP anticipates even greater visibility improvement from BART than modeled since the total annual emissions for NO_X, SO_2 and PM_{10} are about half of the emissions modeled due to more stringent emission limits.

d. Mohave Generating Station

Background: Mohave was a 1,580 MW coal-fired power plant with two units that ceased operations at the end of December 2005. Located about 70 miles southwest of Grand Canyon National Park, Mohave was one of the single, largest sources of SO_2 in the West. The

facility closed after failing to meet emission limitations for SO_2 and emission controls for NO_X as required by a consent decree between the facility's owners and environmental organization.[17] However, the owners did not officially decide to decommission the facility until June 10, 2009. Since Mohave was subject to BART and its final status was unknown at the time Nevada developed its SIP, the WRAP included Mohave in its emission inventory and NDEP prepared a BART determination for SO_2, NO_X and PM_{10} that was required prior to the facility restarting operations. NDEP estimates that BART controls, based on fuel switching from coal to natural gas, would have resulted in an additional reduction of 8,701 tons per year of SO_2 (75 percent reduction) and 19,595 tons per year of NO_X (98 percent reduction) compared to the emission limits and control requirements in the consent decree.

BART Controls: Since Mohave is permanently closed, with emissions of zero, EPA is satisfied with the State's approach to determining BART.

Visibility Improvement: NDEP relies on emission reductions required by the consent decree as well as their BART determination to characterize visibility improvement at eleven Class I areas located within 300 km of Mohave. While this method understates the visibility benefit resulting from the plant's closure, modeling indicates these emission reductions would result in 538 less days every year at the eleven Class I areas with visibility impairment of greater than 0.5 dv. With Mohave's permanent shutdown, the annual emission reductions are equal to the WRAP's baseline emissions for the plant: 55,047 tons of SO_2; 31,344 tons of NO_X; and 3,417 tons of PM_{10}. The closure of the Mohave generating station provided the largest reduction in haze-causing pollutants from a subject-to-BART source in Nevada, and should result in greater visibility improvement than modeling has projected.

4. EPA's Assessment

EPA is proposing to approve NDEP's analyses and conclusions for the BART emissions units at Tracy, Fort Churchill and Reid Gardner generating stations. Based on our review, EPA is proposing to find that the BART determinations were conducted in a manner consistent with the RHR BART requirements in 40 CFR 51.308(e), the EPA's BART Guidelines, and EPA's Air Pollution Control Cost Manual (*http://www.epa.gov/ttnecas1/costmodels.html*). We believe the outcome of Nevada's BART determinations reflects a reasonable consideration of the relevant factors.

F. Determination of Reasonable Progress Goal

The RHR requires states to establish a goal, expressed in deciviews, for each Class I area within the state that provides for reasonable progress toward achieving natural visibility conditions by 2064. The RPG must provide for an improvement in visibility for the most impaired days, and ensure no degradation in visibility for the least impaired days over the period of the SIP.

1. Visibility Projections for 2018

NDEP relied on the Community Multi-Scale Air Quality (CMAQ) model used by the WRAP's RMC to project visibility conditions at all western Class I areas in 2018. For Jarbidge, the model predicted 11.05 dv on the worst days and 2.50 dv on the best days in 2018. The visibility projection compares favorably to the URP estimate in 2018 of 11.09 dv as displayed in Table 9. The visibility projection was based on estimates of emissions reductions from all existing and known controls resulting from Federal and state CAA programs as of March 2007. This data formed the basis for the State's RH SIP submitted to EPA in November 2009.[18] EPA addressed the uncertainties associated with modeled projections by making the RPG an analytic tool for the purpose of evaluating progress, not an enforceable standard. 51.308(d)(1)(v) and 64 FR 35733.

TABLE 9—SUMMARY OF MODEL PREDICTED PROGRESS TOWARD 2018 UNIFORM RATE OF PROGRESS AT JARBIDGE

[In deciviews]

Class I area	20% worst days			20% best days	
	2000–04 Baseline worst days	2018 URP estimate	2018 Modeling result (RPG)	2000–04 Baseline best days	2018 Modeling result
Jarbidge	12.07	11.09	11.05	2.56	2.50

Source: Table 6–3, page 6–15, Nevada RH SIP.

2. Establishing the Reasonable Progress Goal

In setting its RPG of 11.05 dv for Jarbidge, NDEP considered a number of different factors as described on pages 6–16 and 6–17 of the Nevada RH SIP. These factors included: (1) The URP of 11.09 in 2018; (2) Reductions in Nevada's anthropogenic emissions by 2018 estimated at 44 percent for SO_X and 33 percent for NO_X; (3) Reductions in anthropogenic emissions consistent

[17] In a Consent Decree dated December 21, 1999, the owners of Mohave power plant agreed with the Grand Canyon Trust, Sierra Club, and National Parks and Conservation Association to limit opacity to 20 percent by implementing SO_2 emission limitations and NO_X control requirements on units 1 and 2 by December 31, 2005. The consent decree had no emission limitations for either NO_X or PM. EPA promulgated a final rule on February 8, 2002, to include the consent decree requirements in Nevada's Federal Implementation Plan for Visibility at 40 CFR 52.1488. Nevada included the requirements of the Visibility FIP in Mohave's Title V operating permit.

[18] In April 2011, the WRAP issued a draft report regarding an error in its visibility projections for about 15 Class I areas in the West, including Jarbidge. The draft report indicated that, as a result of the error, the projected visibility at Jarbidge in 2018 is 11.8 dv instead of 11.1 dv (rounded up from 11.05 dv). It is EPA's view that at this point in the SIP process, the discovery of a potential error in the visibility projections for 2018 does not call for a revision of the Nevada SIP. Because of the significant resources needed to model projected visibility impacts and the time needed for Nevada to repeat the SIP review and approval process, such action is not appropriate. Moreover, any correction to the modeling results at this time should be based on an update to all the data used in 2007 to model visibility projections. For example, the visibility modeling did not include emission reductions from more recent BART control decisions in Nevada and neighboring states, and did include emissions from proposed facilities in Nevada that now are not expected to be built. EPA is satisfied that the progress report and adequacy determination due in November 2014, see 40 CFR 51.308(g) and (h), will provide an opportunity to determine whether Nevada's SIP is sufficient to ensure that the State is making reasonable progress.

with Nevada's share of emissions reductions at Class I areas in other states; (4) Major reductions in mobile source emissions; (5) Major contributions to visibility impairment from offshore marine shipping and international emissions; (6) Significant contributions from natural sources of visibility impairment; and (7) Consideration of the five BART factors. Based on its analysis of reasonable progress, Nevada concluded that additional control measures, beyond those documented for BART, are unreasonable at this time.

EPA is proposing to agree with the State's analysis and conclusion that it is reasonable not to seek additional controls on other sources within the State at this time. Importantly, the RPG for Jarbidge meets the URP in 2018, committing the State to make reasonable progress in the first planning period toward attaining natural background conditions. Nevada has demonstrated that the RPG provides for visibility improvement on the worst days and no degradation of visibility on the best days compared to the baseline average (see Table 9). The RPG also represents more visibility improvement than would result from implementation of other CAA requirements since emissions reductions from existing and known controls were included in the visibility modeling. EPA finds that the State's decision not to seek additional control measures is supported by the attributes of regional haze at Jarbidge as well as the expected reductions in statewide emissions of SO_X and NO_X and BART controls on three facilities. The WRAP's regional analysis indicates that haze at Jarbidge is mostly from natural sources like wildfires, and most of the anthropogenic sources contributing to that haze are outside the State. Based upon everything NDEP considered in its SIP, EPA is proposing to approve Nevada's demonstration that its RPG provides for reasonable progress in the first planning period as required in CFR 51.308(d)(1)(i), (ii) and (vi).

3. Interstate Consultation

Nevada consulted with thirteen other western states through numerous WRAP meetings, workshops and conference calls that began in 1996. Through the WRAP's consultative process, Nevada resolved technical tasks and policy decisions related to monitoring, emissions, modeling, BART application, control measures, and other issues. There were no comments from other states on Nevada's RH SIP, implying that the consultative process was successful in resolving any potential conflicts that would undermine regional planning. EPA confirms that Nevada consulted with other states on its RPG through the WRAP process, and that there is no evidence of any disagreement on the RPG for Jarbidge.

G. Long-Term Strategy

EPA is proposing to find that NDEP adequately addressed the RHR requirements in developing its LTS. We believe that the LTS provides sufficient documentation to ensure that Nevada will meet its emission reduction obligations for all Class I areas it affects in the first planning period. Nevada relied on monitoring, emission inventories and modeling information from the WRAP as the technical basis for its LTS. Coordination and consultation occurred with other states through the WRAP, in which all western states participated in developing the technical analysis upon which their SIPs are based. This included identifying all anthropogenic sources of visibility impairment including major and minor stationary sources, mobile sources, and area sources. The anticipated net effect on visibility over the first planning period due to changes in point, area and mobile source emissions is a reduction in regional haze at Jarbidge. Nevada also analyzed its contribution to visibility impairment at Class I areas in other states to ensure it is meeting its share of emission reductions obligations.[19] In particular, NDEP considered the following factors in developing its long-term strategy.

1. BART Controls

The installation and operation of BART controls is an integral part of the State's long-term strategy to achieve the RPG at Jarbidge, and to reduce Nevada's share of emissions affecting Class I areas in neighboring states. As described in this notice and in more detail in Nevada's RH SIP, NDEP is requiring three of Nevada Energy's facilities (Tracy, Fort Churchill and Reid Gardner) to install and operate BART controls as expeditiously as practicable, but no later than January 1, 2015 or five years after EPA approval of the SIP, whichever occurs first. Each source is required to establish procedures to ensure that the control equipment is properly operated and maintained. Nevada's BART emissions limitations and schedules for compliance are codified in a revision to the Nevada Administrative Code (NAC) adopted on February 11, 2009.[20] The regulations identify the emission limits and control technologies required as BART on the Tracy, Fort Churchill and Reid Gardner facilities. NDEP also will incorporate BART control limits into Nevada Energy's Title V operating permits for these facilities at the time of renewal. Regarding the Mohave generating station, Nevada terminated its Air Quality Operating Permit No. AP4911–0774 as documented in a letter to Southern California Edison on April 9, 2010.

2. Ongoing Air Pollution Control Programs

Nevada continues to achieve significant reductions in SO_X and NO_X from mobile sources through the implementation of Federal, State and local programs. Federal and State mobile source regulations are the primary air quality programs expected to reduce visibility impairment in the first planning period. These programs include limitations and schedules of compliance identified in rules and regulations that are unique to each program. For example, EPA has mandated new standards for on-road (highway) diesel fuel, known as ultra-low sulfur diesel (ULSD) beginning in 2006. This regulation dropped the sulfur content of diesel fuel from 500 parts per million (ppm) to 15 ppm. ULSD fuel enables the use of cleaner technology diesel engines and vehicles with advanced emissions control devices, resulting in significantly lower emissions. Diesel fuel intended for locomotive, marine and non-road (farming and construction) engines and equipment is required to meet the low sulfur diesel fuel maximum specification of 500 ppm sulfur in 2007, previously 5000 ppm. The ULSD fuel standard of 15 ppm sulfur will apply to all non-road diesel fuel by 2011. Locomotive and marine diesel fuel will be required to meet the ULSD standard beginning in 2012, resulting in further reductions of diesel emissions. Based on WRAP RMC models, implementation of the Federal programs alone will result in a 49 percent reduction in mobile source NO_X emissions and a 63 percent reduction in mobile source SO_X emissions from the baseline to 2018. This trend is expected to provide significant visibility benefits for Jarbidge and at other Class I areas in neighboring states.

The State's continued implementation of the Prevention of Significant Deterioration (PSD) and New Source Review (NSR) program requirements, including FLM involvement in reviewing impacts on Class I areas, also supports achieving visibility goals.

[19] See Summary of Visibility Impairment at Nearby Class I Areas and Nevada's Emissions Reductions, Table 7–6, page 7–21.

[20] See Nevada RH SIP Appendix A for Nevada BART regulations.

These programs will protect the least impaired days from further degradation and will assure that no Class 1 areas experience degradation from expansion or growth of a single new source or the regional development of stationary sources. Nevada also has emission control requirements for motor vehicles in Clark and Washoe Counties; for residential burning in Washoe County; for PM_{10} nonattainment/maintenance areas; and for dust suppression at construction sites and unpaved roads. Together with the State's renewable energy requirements, these ongoing programs will contribute to improvements in visibility at protected Class I areas.

3. Construction Activities

Nevada manages the release of fugitive dust related to construction activities through the implementation of regulations set forth in the Nevada Administrative Code 445B.22037. The State requires fugitive dust to be controlled regardless of the size or amount of acreage disturbed, and requires the use of best practical methods to prevent airborne particulate matter. All activities that have the potential to adversely affect local air quality must include all appropriate measures to limit controllable emissions. Appropriate measures for dust control may consist of a phased approach to acreage disturbance rather than disturbing the entire area all at once; using wet suppression through such application methods as water trucks or water sprays systems to control windblown dust; the application of soil binding agents or chemical surfactant to roadways and areas of disturbed soil; as well as the use of wind-break or wind-limiting fencing designed to limit wind erosion of soils.

4. Source Retirement and Replacement Schedules

While NDEP did not include any repair or replacement schedules for large point sources, EPA is satisfied with the explanation that it is very difficult for the regulatory community to predict potential permit revisions for large sources. In general, repair and replacement of current facilities over time will reduce emissions as new technology is incorporated in industrial processes. Similarly, the construction of new sources may contribute to the early or scheduled retirement of older, less well-controlled sources. Five proposed power plants for Nevada were included in the projected emissions inventory for 2018. Whether these new sources are built will influence the future activity of existing sources.

5. Smoke Management Programs

Preventing and managing emissions from prescribed fires in Nevada is achieved through implementation of the Nevada Smoke Management Program (SMP) and through Open Burning regulations. The State's SMP was developed to coordinate and facilitate the statewide management of prescribed outdoor burning, specifically for land management purposes. This program is designed to meet the requirements of Nevada's air quality statutes listed in Nevada Revised Statutes (NRS) 445B.100 through 445B.845, inclusive, and the requirements of the USEPA Interim Air Quality Policy on Wild Land and Prescribed Fires (EPA OAQPS, April 23, 1998). The SMP supports the visibility protection goals for Class I areas. This program does not, however, supersede the authority of local governments to regulate and control smoke and air pollution under NRS 244.361 and NRS 268.410 or the authority of the State forester to regulate controlled fires under NRS 527.122 through 527.128.

Open burning is controlled through a comprehensive set of regulations that are found in NAC 445B.22067. These regulations apply to Federal, state and private lands and prohibit open burning of combustible refuse, waste, garbage, oil or open burning for any salvage operation. Exemptions are granted for open burning conducted for the purposes of weed abatement, conservation, disease control, game or forest management, and fire training. Burning for agricultural purposes is exempt, as is the burning of yard waste and untreated wood at single-family residences. Small fires used for cooking, recreation, education or ceremonial purposes are also exempt.

6. Other Measures Supporting the LTS

NDEP intends to evaluate additional controls for sources that impact visibility in Class I areas in the required progress report due in 2014. This evaluation will take into account new monitoring and modeling information, new regulations, and new guidance that may result in additional control measures consistent with the reasonable progress requirement of the RHR. If additional controls are identified, the progress report will update the plan to include an implementation schedule for controls, necessary rulemaking, projected visibility improvements, and revised RPGs for 2018.

7. Interstate Transport Requirements for Visibility

Section 110(a)(2)(D)(i)(II) of the Act requires SIP revisions to contain adequate provisions to prohibit any source or other types of emission activity within the state from emitting any air pollutant in amounts that will interfere with another state's plan to protect visibility. Nevada submitted its SIP for Interstate Transport to EPA on February 7, 2007, which EPA approved and promulgated in the **Federal Register** on July 31, 2007 (70 FR 41629). In our **Federal Register** Notice, we deferred action on whether Nevada interferes with other states' plans to address regional visibility impairment caused by regional haze until we received Nevada's Regional Haze SIP. As explained in Section IV.D.2. of this notice, NDEP relied on the WRAP's source apportionment modeling to demonstrate that Nevada's emissions are projected to have a minimal contribution to sulfate and nitrate extinction in each of 24 Class I areas in five adjacent states. Moreover, none of the neighboring western states have requested emission reductions from Nevada in order to meet their RPGs. Therefore, in proposing to approve Nevada's RH SIP, we are proposing to find that this plan revision contains adequate provisions to protect visibility in other states.

H. Monitoring Strategy

Nevada's SIP includes the required monitoring strategy for measuring, characterizing and reporting on regional haze visibility impairment as required in 51.308(d)(4). The primary source of monitoring data for the regional haze program in Nevada is the IMPROVE network. There is currently one IMPROVE monitoring site at Jarbidge. IMPROVE monitoring data serves as the baseline for the regional haze program, and is the source of data for states to comply with the regional haze monitoring requirements now and in the future. States have access to the IMPROVE data and data analysis tools through the Visibility Information Exchange Web System (VIEWS), which is maintained by the WRAP and other regional planning organizations. The operation of the IMPROVE network is dependent on EPA funding.

1. Coordination of RAVI With RHR

Nevada's monitoring strategy is coordinated with the monitoring required for Reasonably Attributable Visibility Impairment (RAVI) that is codified under a Federal Implementation Plan (FIP) for the State.

RAVI, which predates the RHR, is visibility impairment that is caused by the emission of air pollutants from one or a small number of sources. The provisions of visibility monitoring for RAVI in 40 CFR 52.26 are incorporated into the visibility FIP for Nevada in 40 CFR 52.1488. Under the FIP, EPA has responsibility in cooperation with the appropriate FLMs to monitor visibility in Nevada's Class I area. NDEP coordinates its regional haze monitoring with the FIP for RAVI by participating in the IMPROVE network, and utilizing data from the same IMPROVE monitor at Jarbidge.

2. Additional Monitoring Sites

EPA agrees with Nevada's assessment that the existing IMPROVE monitor at Jarbidge, its only class I area, is sufficient to address regional haze and determine reasonable progress toward the national visibility goal. The monitor is located in the Humboldt National Forest in northeastern Nevada, about one kilometer north of the city of Jarbidge in the Jarbidge River drainage.

3. Using and Reporting Monitoring Data

Nevada will continue to rely on the IMPROVE network, technical support from the WRAP, and regional technical tools (*e.g.,* VIEWS and WRAP's Technical Support System) to assess the contribution of emissions to visibility impairment at Class I areas within and outside the State. The IMPROVE network was established in the 1980s to measure visibility impairment in mandatory class I areas throughout the United States. The IMPROVE monitors were used by WRAP and NDEP as the source of data for the 2000–2004 baseline and for future projections, and is the source of record for air quality professionals to track visibility improvement or degradation. Visibility monitoring data is available to the public, states and EPA in an electronic format at the IMPROVE and VIEWS Web sites

4. Statewide Emissions Inventory

NDEP commits to updating periodically its statewide emissions inventory, tracking emissions changes, determining trends, and utilizing the WRAP's services to evaluate reasonable progress. Nevada has a statewide emissions inventory of pollutants reasonably anticipated to cause or contribute to visibility impairment as described in section III.B. of this notice. NDEP annually updates its inventory of major point sources and its entire inventory every three years as required by EPA's Consolidated Emissions Reporting Rule. The State's capacity to fulfill future requirements to project emissions and evaluate progress depend on the continued existence of the IMPROVE program as well as the technical support of the WRAP or a similar regional planning organization

I. State and Federal Land Manager Coordination

Nevada participated fully in the WRAP process, the primary forum for consultation among western states, Tribal nations, Federal agencies, stakeholder groups and the public. FLMs from the National Park Service, U.S. Fish and Wildlife Service, Bureau of Land Management and the U.S. Forest Service were actively engaged in the WRAP's development of technical analyses and reports for the western region and individual states. To facilitate consultation, NDEP provided a list of its agency contacts to the FLMs in a letter dated September 15, 2006. The FLMs had numerous opportunities throughout the WRAP process to participate fully in the development and review of regional technical documents that form the basis of the western states' plans. Nevada provided additional opportunities for coordination and consultation with FLMs through local meetings and stakeholder workshops. NDEP provided its draft RH SIP to the FLMs on January 5, 2009 for a 60-day review and comment period. Comments were received from the FLMs on March 4 and 6, 2009. NDEP's responses to the FLMs' comments are in Appendix C of the Nevada RH SIP. EPA believes that NDEP adequately addressed the FLMs' concerns either through revisions to the SIP, or in responses to their comments. NDEP also has committed to provide the FLMs an opportunity to review and comment on future SIP revisions, the 5-year progress reports, and the implementation of other programs that may contribute to class I visibility impairment. All SIP revisions will include a description of how the state consulted with and addressed any comments provided by the FLMs. At a minimum, NDEP will meet with the FLMs on an annual basis through the WRAP, as long as the WRAP continues to provide this forum. EPA is satisfied that Nevada has coordinated with the FLMs as required in 40 CFR 51.308(i)(1–4).

J. Periodic SIP Revisions and 5-Year Progress Reports

Nevada affirmed its commitment to submit a report to EPA every five years evaluating progress toward the RPG for its Class I area as well as Class I areas outside the State that may be affected by emissions from within the State as required in 40 CFR 51.308(g). The first report is due five years after the State's submittal, which is November 18, 2014. The required elements for these reports are listed in section III of this notice.

Nevada commits to making an adequacy determination of the current SIP at the same time it submits the five-year progress report as required in 40 CFR 51.308(h). If Nevada determines that the current implementation plan is or may be inadequate due to emissions from within the State, Nevada will develop additional strategies to address the plan deficiencies and revise the SIP within one year from the date that the progress report is due. If Nevada determines that the plan is or may be inadequate due to emissions from other states, Nevada will notify EPA and the other states. The affected states are required to address the deficiency through the regional planning process by developing additional strategies.

Nevada also commits to complete and submit a comprehensive RH SIP revision to EPA by July 31, 2018 and every 10 years thereafter as required in 40 CFR 51.308(f). In these comprehensive revisions, the State must evaluate and reassess all of the elements required in 40 CFR 51.308(d), taking into account improvements in monitoring data collection and analysis techniques and control technologies. The State must also address current visibility conditions, actual progress toward natural conditions, effectiveness of the long-term strategy, and the reasonable progress goal.

V. EPA's Proposed Action

EPA believes the Nevada RH SIP fulfills all the relevant requirements of CAA Section 169A and the Regional Haze Rule. Therefore, we are proposing a full approval of the plan as described in Section 110(k)(3) of the Act. Regarding the major requirements, we find that Nevada has: established baseline visibility conditions and a reasonable progress goal for its one Class I area; developed a long-term strategy with enforceable measures to ensure reasonable progress toward achieving the RPG in the first planning period ending in 2018; adequately applied Best Available Retrofit Technology to specific stationary sources; developed a regional haze monitoring strategy; provided for periodic progress reports and revisions; provided for consultation and coordination with Federal land managers; and provided for the regional haze plan's future review and revisions. We also are proposing to find that emissions from Nevada do not interfere with other states' measures to protect

visibility as required by CAA Section 110(a)(2)(D)(i)(II).

VI. 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 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'' 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 (Pub. L. 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 interfere with Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) because EPA lacks the discretionary authority to address environmental justice in this rulemaking.

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, Intergovernmental relations, Nitrogen oxides, Sulfur dioxide, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: June 9, 2011.

Jared Blumenfeld,

Regional Administrator, Region 9.

[FR Doc. 2011–15238 Filed 6–21–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2011–0386–201137; FRL-9322–5]

Approval and Promulgation of Air Quality Implementation Plans; North Carolina: Clean Smokestacks Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of North Carolina for the purpose of establishing in North Carolina's SIP the system-wide emission limitations from the North Carolina Clean Smokestacks Act (CSA). On August 21, 2009, the State of North Carolina, through the North Carolina Department of Environment and Natural Resources (NC DENR), Division of Air Quality (DAQ), submitted an attainment demonstration for the Hickory-Morganton-Lenoir and Greensboro-Winston Salem-High Point 1997 fine particulate matter ($PM_{2.5}$) nonattainment areas. That submittal includes a request that the system-wide emission limitations from the North Carolina CSA be incorporated into the State's Federally approved SIP. EPA proposes to determine that the SIP revision is approvable pursuant to the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before July 22, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2011–0386, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *E-mail: spann.jane@epa.gov.*
3. *Fax:* (404) 562–9029.
4. *Mail:* EPA–R04–OAR–2011–0386, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960.
5. *Hand Delivery or Courier:* Jane Spann, Acting Chief, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. ''EPA–R04–OAR–2011–0386.'' EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

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

FOR FURTHER INFORMATION CONTACT: Joel Huey or Nacosta C. Ward, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Mr. Huey may be reached by phone at (404) 562–9104. Mr. Huey can also be reached via electronic mail at *huey.joel@epa.gov*. Ms. Ward may be reached by phone at (404) 562–9140 or via electronic mail at *ward.nacosta@epa.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. What action is EPA proposing to take?
II. What is the background of North Carolina's CSA?
III. What are the general requirements of North Carolina's CSA?
IV. Why is EPA proposing this action?
V. Proposed Action
VI. Statutory and Executive Order Reviews

I. What action is EPA proposing to take?

EPA is proposing to approve a revision to the North Carolina SIP to incorporate the system-wide emission limitations (or caps) from the State's CSA. The specific provisions being incorporated into the SIP are paragraphs (a) through (e) of Section 1 of Session Law 2002–4, Senate Bill 1078 (hereafter ''Senate Bill 1078'') enacted June 20, 2002. This proposed approval does not include incorporation into the North Carolina SIP of paragraphs (f) through (j) of Section 1 of Senate Bill 1078 nor any of Section 2 of Senate Bill 1078. Please refer to the docket for this rulemaking for the complete text of these provisions.

II. What is the background of North Carolina's CSA?

In June 2002, the General Assembly of North Carolina, Session 2001, passed Session Law 2002–4, also known as Senate Bill 1078. This legislation, entitled *''An Act to Improve Air Quality in the State by Imposing Limits on the Emission of Certain Pollutants from Certain Facilities that Burn Coal to Generate Electricity and to Provide for Recovery by Electric Utilities of the Costs of Achieving Compliance with Those Limits,''* requires significant actual emission reductions from coal-fired power plants in North Carolina. The State expected that emission reductions from the CSA would have significant health benefits for the citizens of North Carolina and other states.

North Carolina's CSA includes a schedule of system-wide caps on emissions of nitrogen oxides (NO_X) and sulfur dioxide (SO_2) from coal-fired power plants in the State, the first of which became effective in 2007. The State expected the resulting emission reductions would serve as a significant step towards meeting the 1997 $PM_{2.5}$ and 8-hour ozone national ambient air quality standards (NAAQS), among other NAAQS, improving visibility in the mountains and other scenic vistas, and reducing acid rain. Reducing NO_X and SO_2 emissions, using certain technologies, also has the co-benefit of reducing mercury emissions. EPA notes that all areas in the State that were designated nonattainment for the 1997 $PM_{2.5}$ and 8-hour ozone NAAQS are now attaining the standards. Although the Hickory-Morganton-Lenoir and Greensboro-Winston Salem-High Point nonattainment areas for the 1997 $PM_{2.5}$ NAAQS have not yet been redesignated to attainment, EPA determined that these areas had attaining data based on the three-year period 2006–2008.[1] Also, although the Charlotte 1997 8-hour ozone nonattainment area is still designated nonattainment, EPA has issued a proposed determination that the Area has attaining data based on the 2008–2010 design value period. *See* 76 FR 20293 (April 12, 2011). North Carolina has identified the CSA as part of its plan to attain and maintain the NAAQS. Because North Carolina is relying on emissions reductions from the CSA to demonstrate attainment and maintenance for certain areas in the State, North Carolina is now formally seeking that the CSA be included in the SIP so that the CSA's requirements may be considered ''permanent and enforceable.''

III. What are the general requirements of North Carolina's CSA?

North Carolina's CSA applies to the two investor-owned public utilities in North Carolina that own or operate coal-fired generating units with the capacity to generate 25 or more megawatts of electricity: Progress Energy Carolinas, Inc. (Progress Energy) and Duke Power, a division of Duke Energy Corporation (Duke Energy). Although the emission caps apply collectively to each investor-owned public utility, the CSA has no provision for the trading of pollution credits from one utility to another. Tables 1 and 2 below summarize the schedule for implementation of the NO_X and SO_2 emission caps required by the CSA.

TABLE 1—NO_X EMISSION CAPS FOR INVESTOR-OWNED PUBLIC UTILITIES THAT OWN OR OPERATE COAL-FIRED GENERATING UNITS

Investor-owned public utilities that collectively emitted in calendar year 2000	Collective calendar year emission caps beginning January 1, 2007	Collective calendar year emission caps beginning January 1, 2009
More than 75,000 tons of NO_X	35,000 tons of NO_X	31,000 tons of NO_X.
Equal to or less than 75,000 tons of NO_X	25,000 tons of NO_X	Unchanged from 2007 cap.

[1] EPA's determination that the Hickory-Morganton-Lenoir and Greensboro-Winston Salem-High Point $PM_{2.5}$ nonattainment areas have attained the 1997 $PM_{2.5}$ NAAQS is not equivalent to the redesignation of the areas to attainment. The designation status of the areas remains nonattainment for the 1997 $PM_{2.5}$ NAAQS until such time as EPA determines that the areas meet all of the CAA requirements for redesignation to attainment. See 75 FR 54 (January 4, 2010) and 75 FR 230 (January 5, 2010), respectively.

TABLE 2—SO_2 EMISSION CAPS FOR INVESTOR-OWNED PUBLIC UTILITIES THAT OWN OR OPERATE COAL-FIRED GENERATING UNITS

Investor-owned public utilities that collectively emitted in calendar year 2000	Collective calendar year emission caps beginning January 1, 2009	Collective calendar year emission caps beginning January 1, 2013
More than 225,000 tons of SO_2	150,000 tons of SO_2	80,000 tons of SO_2.
Equal to or less than 225,000 tons of SO_2	100,000 tons of SO_2	50,000 tons of SO_2.

According to documentation submitted by North Carolina, applicable utilities in North Carolina subject to the CSA must: (1) Reduce actual emissions of NO_X from 245,000 tons in 1998 to 56,000 tons by 2009 (a 77 percent reduction); and (2) reduce actual SO_2 emissions from 489,000 tons in 1998 to 250,000 tons by 2009 (a 49 percent reduction) and to 130,000 tons by 2013 (a 73 percent reduction). This represents about a one-third reduction of the total NO_X emissions and a one-half reduction of the total SO_2 emissions from all sources in North Carolina. Table 3 below lists the coal-fired power plants in North Carolina subject to the CSA.

TABLE 3—COAL-FIRED POWER PLANTS SUBJECT TO NORTH CAROLINA'S CSA

Plant	Parent company	Location
Allen	Duke Energy	Belmont.
Belews Creek	Duke Energy	Walnut Cove.
Buck	Duke Energy	Salisbury.
Cliffside	Duke Energy	Cliffside.
Dan River	Duke Energy	Eden.
Marshall	Duke Energy	Terrell.
Riverbend	Duke Energy	Mount Holly.
Ashville	Progress Energy	Arden.
Cape Fear	Progress Energy	Moncure.
Lee	Progress Energy	Goldsboro.
Mayo	Progress Energy	Roxboro.
Roxborro	Progress Energy	Semora.
L.V. Sutton	Progress Energy	Wilmington.
Weatherspoon	Progress Energy	Lumberton.

As noted above, this proposed approval does not include incorporation into the North Carolina SIP paragraphs (f) through (j) of Section 1 of Senate Bill 1078. These provisions of the State's law, which North Carolina did not request to be incorporated into the State's Federally-approved SIP, stipulate requirements regarding several aspects of implementation of the CSA. In brief, those requirements provide that: (1) Affected utilities may determine how compliance with the collective emissions limitations may be achieved and that CSA does not alter obligations to comply with any other Federal or state law or the authority of the Commission to impose specific limitations on the emissions of NO_X and SO_2; (2) a subject emission unit shall remain subject to the collective emissions limitations whether or not it continues to be owned or operated by an investor-owned public utility; (3) any permit or modified permit issued for a subject unit shall include conditions that provide for testing, monitoring, record keeping, and reporting adequate to assure compliance with the CSA requirements; (4) the Governor may enter into an agreement with an investor-owned public utility for the purpose of transferring to the State any trading program emission allowances that result from compliance with the CSA; and (5) a subject investor-owned public utility shall submit to the State an annual verified statement providing details of activities related to compliance with CSA. As also noted above, this proposed approval does not include incorporation into the North Carolina SIP any of Section 2 of Senate Bill 1078, which stipulates the permitting requirements for all air contaminant sources in the State of North Carolina. Nonetheless, the emission reductions are the key component of the CSA, and North Carolina relies on the reductions to demonstrate attainment and maintenance with the NAAQS. Thus, inclusion of the emission reductions into the SIP serves the purpose of making the reductions permanent and enforceable as well as providing a Federal source of applicable requirements for title V permitting and other purposes.

IV. Why is EPA proposing this action?

The purpose of today's proposed approval is to make the CSA emissions reductions Federally enforceable (and permanent) because those reductions are part of North Carolina's plan to attain and maintain the NAAQS. NC DENR requested that specific provisions of the CSA be formally adopted into the North Carolina SIP in support of its attainment demonstrations for the 1997 $PM_{2.5}$ NAAQS for both the Hickory-Morganton-Lenoir and Greensboro-Winston Salem-High Point nonattainment areas. Such inclusion is consistent with the requirements of the CAA. Under section 110(l) of the CAA, EPA may not approve a revision to a SIP if it would interfere with any applicable requirement concerning NAAQS attainment and reasonable further progress, or any other applicable requirement of the CAA. In reducing system-wide NO_X and SO_2 emissions allowed by coal-fired power plants in the State, the CSA is clearly a strengthening of the North Carolina's SIP and will not interfere with CAA requirements. In addition, Federal approval of the CSA will ensure the State may take credit for the associated NO_X and SO_2 emission reductions when pertinent to SIP submittals for other CAA requirements.

V. Proposed Action

EPA is proposing to approve the portion of North Carolina's August 21, 2009, SIP revision which incorporates

the system-wide emission caps from the State legislation entitled, *''An Act to Improve Air Quality in the State by Imposing Limits on the Emission of Certain Pollutants from Certain Facilities that Burn Coal to Generate Electricity and to Provide for Recovery by Electric Utilities of the Costs of Achieving Compliance with Those Limits.''* The specific provisions being proposed for incorporation into the SIP are paragraphs (a) through (e) of Section 1 of Session Law 2002–4, Senate Bill 1078 enacted June 20, 2002. Once this provision is adopted into the SIP, the collective emission caps applicable to each investor-owned public utility will be permanent and Federally enforceable.

VI. 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 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 (Pub. L. 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.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

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

Dated: June 9, 2011.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 2011–15636 Filed 6–21–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2011–0411; FRL–9321–6]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Adoption of the Revised Nitrogen Dioxide Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia for the purpose of adding the new 1-hour nitrogen dioxide (NO_2) standard at a level of 100 parts per billion (ppb) and updating the list of Federal documents incorporated by reference. In the Final Rules section of this **Federal Register**, EPA is approving the Commonwealth's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by July 22, 2011.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2011–0411 by one of the following methods:

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

B. *E-mail: fernandez.cristina@epa.gov.*

C. *Mail:* EPA–R03–OAR–2011–0411, Cristina Fernandez, Associate Director, Office of Air Program Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2011–0411. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an anonymous access system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to

technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Gregory Becoat, (215) 814–2036, or by e-mail at *becoat.gregory@epa.gov.*

SUPPLEMENTARY INFORMATION:

For further information, please see the information provided in the direct final action, with the same title, ''Approval and Promulgation of Air Quality Implementation Plans; Virginia; Adoption of the Revised Nitrogen Dioxide Standards and Update of Appendices,'' that is located in the Rules and Regulations section of this **Federal Register** publication.

Dated: June 6, 2011.

W.C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2011–15456 Filed 6–21–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 98

[EPA–HQ–OAR–2009–0927; FRL–9322–2]

RIN A2060

Mandatory Reporting of Greenhouse Gases; Changes to Provisions for Electronics Manufacturing (Subpart I) To Provide Flexibility

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing changes to the calculation and monitoring provisions in the Electronics Manufacturing portion (Subpart I) of the Mandatory Greenhouse Gas Reporting Rule for the ''largest'' semiconductor manufacturing facilities (*i.e.,* those that fabricate devices on wafers measuring 300 millimeters or less in diameter and that have an annual manufacturing capacity of greater than 10,500 square meters). More specifically, for reporting years 2011 and 2012 this action proposes to allow the largest semiconductor facilities the option to calculate emissions using default emission factors already contained in Subpart I, instead of recipe-specific utilization and by-product formation rates (recipe-specific emission factors) for the plasma etching process type. These proposed changes are in response to a request for reconsideration of specific provisions submitted by the Semiconductor Industry Association. This action would only apply to the initial years of compliance while the Agency continues to better understand industry's concerns with Subpart I and considers longer-term alternative options.

DATES: *Comments.* Comments must be received on or before July 22, 2011.

Public Hearing. EPA does not plan to conduct a public hearing unless requested. To request a hearing, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section by June 29, 2011. If requested, the hearing will be conducted July 7, 2011, in the Washington, DC area. If a hearing is held, EPA will accept comments that rebut or supplement information presented at the hearing through August 8, 2011. EPA will provide further information about the hearing on its Web page if a hearing is requested.

ADDRESSES: You may submit your comments, identified by Docket ID No. EPA–HQ–OAR–2009–0927 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *E-mail: GHGReportingFGHG@epa.gov.* Include docket ID No. EPA–HQ–OAR–2009–0927 [and/or RIN number 2060–XXXX] in the subject line of the message.
- *Fax:* (202) 566–9744.
- *Mail:* Environmental Protection Agency, EPA Docket Center (EPA/DC), Mailcode 28221T, Attention Docket ID No. EPA–HQ–OAR–2009–0927, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.
- *Hand/Courier Delivery:* EPA Docket Center, Public Reading Room, EPA West Building, Room 3334, 1301 Constitution Avenue, NW., Washington, DC 20004. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2009–0927. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

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 Docket, EPA/DC, EPA West Building, Room 3334, 1301 Constitution Ave., NW., Washington, DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Ms. Carole Cook, Climate Change Division, Office of Atmospheric Programs (MC–6207J), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number (202) 343–9263; fax (202) 343–2342; e-mail address: *GHGReportingRule@epa.gov.* For technical information, please go to the Greenhouse Gas Reporting Rule Program Web site *http://www.epa.gov/climatechange/emissions/ghgrulemaking.html.* To submit a question, select Rule Help Center, followed by Contact Us. To obtain information about the public hearing or to register to speak at the hearing, please go to *http://www.epa.gov/climatechange/emissions/ghgrulemaking.html.* Alternatively, contact Carole Cook at 202–343–9263.

Worldwide Web (WWW). In addition to being available in the docket, an electronic copy of this proposal will also be available through the WWW. Following the Administrator's signature, a copy of this action will be posted on EPA's Greenhouse Gas Reporting Program Web site at *http://www.epa.gov/climatechange/emissions/ghgrulemaking.html.*

SUPPLEMENTARY INFORMATION:

Additional Information on Submitting Comments: To expedite review of your comments by Agency staff, you are encouraged to send a separate copy of your comments, in addition to the copy you submit to the official docket, to Carole Cook, U.S. EPA, Office of Atmospheric Programs, Climate Change Division, Mail Code 6207–J, Washington, DC 20460, telephone (202) 343–9263, e-mail address: *GHGReportingRule@epa.gov.*

Regulated Entities. The Administrator determined that this action is subject to the provisions of Clean Air Act (CAA) section 307(d). See CAA section 307(d)(1)(V) (the provisions of section 307(d) apply to ''such other actions as the Administrator may determine''). These are proposed changes to existing regulations. If finalized, these amended regulations would affect owners or operators of certain manufacturers of electronic devices. Regulated categories and examples of affected entities include those listed in Table 1 of this preamble:

TABLE 1—EXAMPLES OF AFFECTED ENTITIES BY CATEGORY

Category	NAICS	Examples of affected facilities
Electronics Manufacturing	334111	Microcomputer manufacturing facilities.
	334413	Semiconductor, photovoltaic (solid-state) device manufacturing facilities.
	334419	Liquid Crystal Display (LCD) unit screens manufacturing facilities.
	334419	Micro-electro-mechanical systems (MEMS) manufacturing facilities.

Although Table 1 of this preamble lists the types of facilities that could be potentially affected by this action, other types of facilities not listed in the table could also be affected. To determine whether you are affected by this action, you should carefully examine the applicability criteria found in 40 CFR part 98, subpart I or the relevant criteria in the sections related to electronics manufacturing. If you have questions regarding the applicability of this action to a particular facility or supplier, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** Section.

Acronyms and Abbreviations. The following acronyms and abbreviations are used in this document.

BAMM ..	best available monitoring methods
CAA	Clean Air Act
CBI	confidential business information
CFR	Code of Federal Regulations
EO	Executive Order
EPA	U.S. Environmental Protection Agency
FR	FEDERAL REGISTER
GHG	greenhouse gas
m^2	square meters
mm	millimeter
OMB	Office of Management and Budget
RFA	Regulatory Flexibility Act
RIA	Regulatory Impact Analysis
SBA	Small Business Administration
SBREFA	Small Business Regulatory Enforcement and Fairness Act
U.S.	United States
UMRA ..	Unfunded Mandates Reform Act of 1995
USC	United States Code

Table of Contents

I. Background
A. Organization of This Preamble
B. Background on This Action
C. Legal Authority
II. Proposed Revisions to Subpart I of 40 CFR part 98
A. Proposed Changes to Subpart I Provisions for the Largest Semiconductor Manufacturing Facilities
B. Subpart I BAMM Provisions
C. Apportioning Model Verification
III. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act (RFA)
D. Unfunded Mandates Reform Act (UMRA)
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

I. Background

A. Organization of This Preamble

The first section of this preamble contains the basic background information about the origin of these proposed rule amendments and request for public comment. This section also discusses EPA's use of our legal authority under the Clean Air Act to collect data under the Mandatory Reporting of Greenhouse Gases rule.

The second section of this preamble describes in detail the changes that are being proposed to Subpart I. In addition, this section presents EPA's rationale for the proposed changes, and also describes related actions affecting Subpart I that are published in a separate notice in today's **Federal Register**.

Finally, the last (third) section of the preamble discusses the various statutory and executive order requirements applicable to this proposed rulemaking.

B. Background on This Action

On October 30, 2009, EPA published a rule for the mandatory reporting of GHGs (also referred to as 40 CFR part 98 or part 98) from large GHG emission sources and suppliers in the United States (74 FR 56260). The rule requires annual reporting to EPA of GHG emissions and supply from certain sectors of the economy, and applies to certain downstream facilities that emit GHGs, as well as to certain upstream

suppliers of products that will result in GHG emissions when combusted, released or oxidized. Part 98 regulations require only that source categories subject to the rule monitor and report GHGs in accordance with the methods specified in the individual subparts.

EPA initially proposed reporting requirements for electronics manufacturing on April 12, 2009 (74 FR 16448) as part of a larger rulemaking effort to establish a GHG reporting program for all sectors of the economy. However, EPA did not include requirements for electronics manufacturing, along with several other source categories, in the final part 98 in October 2009 because EPA received a number of lengthy, detailed comments regarding the proposed requirements.

On April 12, 2010, EPA published a revised proposal (75 FR 18652) concerning the monitoring and reporting methods for electronics manufacturing facilities. After considering public comments on the revised proposal, EPA published Subpart I: Electronics Manufacturing of the Greenhouse Gas Reporting Rule on December 1, 2011 (40 CFR part 98, subpart I) (75 FR 74774) (Subpart I).

In that rule, among other provisions, EPA finalized two different methods for facilities that manufacture semiconductors wafers measuring 300 millimeters (mm) or less in diameter to calculate and report their fluorinated GHGs, depending on the facility's manufacturing capacity: (1) A method for facilities that have an annual manufacturing capacity that is less than or equal to 10,500 square meters (m^2) of substrate (hereinafter referred to as ''other semiconductor manufacturing facilities''), and (2) a method for those that have an annual manufacturing capacity greater than 10,500 m^2 of substrate (hereinafter referred to as the ''largest semiconductor manufacturing facilities''). Pursuant to 40 CFR 98.93(a)(2)(i), semiconductor manufacturing facilities that fabricate devices on wafers measuring 300 mm or less in diameter and that have an annual manufacturing capacity of less than or equal to 10,500 m^2 of substrate must calculate and report their fluorinated GHG emissions using default emission factors for the following five process types and sub-types:

- Plasma etching process type.
- Chamber cleaning process type, which includes the following three process sub-types:

—In-situ plasma chamber cleaning process sub-type.
—Remote plasma chamber cleaning process sub-type.
—In-situ thermal chamber cleaning process sub-type.

- Wafer cleaning process type.

Pursuant to 40 CFR 98.93(a)(2)(ii), semiconductor manufacturing facilities that fabricate devices on wafers measuring 300 mm or less in diameter and that have an annual manufacturing capacity greater than 10,500 m^2 of substrate (*i.e.,* the largest semiconductor manufacturing facilities) must calculate and report their emissions using a combination of default emission factors and directly measured recipe-specific emission factors. For the following four process types and sub-types, the largest semiconductor manufacturing facilities must calculate emissions using only the default emission factors:

- Chamber cleaning process type which includes the following three process sub-types:

—In-situ plasma chamber cleaning process sub-type.
—Remote plasma chamber cleaning process sub-type.
—In-situ thermal chamber cleaning process sub-type.

- Wafer cleaning process type.

For the plasma etching process type, the largest semiconductor manufacturing facilities are required to calculate emissions using only directly measured recipe-specific emission factors.

EPA also included provisions for all electronics manufacturing facilities to use and/or request the use of best available monitoring methods (BAMM) in lieu of following specified parameters for calculating GHG emissions for a specific period of time. To estimate emissions from January 1, 2011 through June 30, 2011, owners or operators may use BAMM for any parameter that cannot reasonably be measured according to the monitoring and QA/QC requirements of Subpart I without submitting a request and receiving approval from the EPA Administrator (40 CFR 98.94(a)(1)). To extend the use of BAMM to estimate emissions that occur beyond June 30, 2011, owners and operators must submit a request and receive approval from the Administrator consistent with the following:

- Requests for extension of the use of BAMM to estimate emissions that occur from July 1, 2011 through December 31, 2011 for parameters other than recipe-specific utilization and by-product formation rates for the plasma etching process type must have been submitted to EPA no later than February 28, 2011 (40 CFR 98.94(a)(2)).
- Requests for extension of the use of BAMM to estimate emissions that occur from July 1, 2011 through December 31, 2011 for recipe-specific utilization and by-product formation rates for the plasma etching process type must be submitted to EPA no later than June 30, 2011 (40 CFR 98.94(a)(3));
- Requests for extension of the use of BAMM to estimate emissions beyond December 31, 2011 for unique and extreme circumstances must be submitted to EPA no later than June 30, 2011 (40 CFR 98.94(a)(4)).

Following the publication of Subpart I in the **Federal Register**, the Semiconductor Industry Association (SIA) sought reconsideration of several provisions in the final rule. In particular, in their Petition (available in docket EPA–HQ–OAR–2009–0927), SIA raised concerns about the individual recipe measurement approach, that is, the requirement that the largest facilities develop and use recipe-specific emission factors for etch processes. More specifically, SIA stated that the individual recipe measurement approach is technically impractical, burdensome, threatens intellectual property, and would hamper innovation. SIA stated, ''* * * Final Subpart I suffers from serious flaws relating to the infeasibility of compliance with a recipe-based emission reporting requirement; the incompatibility of a recipe-based emission reporting requirement to the semiconductor manufacturing process; the serious confidentiality concerns relating to the sharing of intellectual property inherent to a recipe-based reporting requirement; and the grossly understated compliance costs contained in EPA's economic analysis.''

SIA reported that a manufacturer may run hundreds to thousands of different recipes per year. They argued that determining the utilization and by-product formation rates for each recipe would present an unreasonable cost and technical burden on reporting facilities. They also argued that the burden is compounded by the fact that hundreds of recipes may be added every year, for which new factors would need to be determined. To support their arguments, SIA provided the results of a survey of industry members regarding the number of recipes for which factors would need to be determined, and a cost estimate of the final reporting requirements (for more information, please see SIA's Petition for Reconsideration available in docket EPA–HQ–OAR–2009–0927).

In addition to their concerns about the recipe-specific measurements, SIA also specifically cited the BAMM provisions and their timing as problematic. In particular, SIA stated that the BAMM provisions raise ''substantive compliance issues.'' SIA stated that the substantive compliance issues relate to the following aspects of the BAMM provisions: The requirement to recalculate and resubmit estimated

emissions, the individual requirement-by-requirement BAMM request process, the documentation requirement, the timeframe for assembling the documentation, and the unique and extreme circumstances provision. Further, SIA stated that the deadlines for submitting the request to use BAMM were ''unreasonable.''

C. Legal Authority

EPA is proposing these rule amendments under its existing CAA authority, specifically authorities provided in CAA section 114.

As stated in the preamble to the 2009 final rule (74 FR 56260) and the Response to Comments on the Proposed Rule, Volume 9, Legal Issues, CAA section 114 provides EPA broad authority to require the information proposed to be gathered by this rule because such data would inform and are relevant to EPA's carrying out a wide variety of CAA provisions. As discussed in the preamble to the initial proposed rule (74 FR 16448, April 10, 2009), CAA section 114(a)(1) authorizes the Administrator to require emissions sources, persons subject to the CAA, manufacturers of control or process equipment, or persons whom the Administrator believes may have necessary information to monitor and report emissions and provide such other information the Administrator requests for the purposes of carrying out any provision of the CAA. For further information about EPA's legal authority, see the preambles to the 2009 proposed and final rules and EPA's Response to Comments, Volume 9.[1]

II. Proposed Revisions to Subpart I of 40 CFR part 98

A. Proposed Changes to Subpart I Provisions for the Largest Semiconductor Manufacturing Facilities

In this action, EPA is proposing to amend Subpart I to allow the largest semiconductor manufacturing facilities[2] flexibility in the initial years of compliance to estimate fluorinated GHG emissions from the plasma etching process type. Specifically, EPA is proposing to amend 40 CFR 98.93(a)(2)(ii) so that the largest semiconductor manufacturing facilities may use the same methods for estimating emissions from clean and etch processes as the other semiconductor manufacturing facilities for reporting years 2011 and 2012. EPA is proposing this action in response to a request for reconsideration of specific provisions, including the provisions requiring the largest facilities to use recipe-specific emission factors and the BAMM provisions.

Under this proposal, for reporting years 2011 and 2012, the largest semiconductor manufacturing facilities would be able to use the default utilization and by-product formation rates already contained within Subpart I in Tables I–3 and I–4 to estimate fluorinated GHG emissions for the plasma etching process type, instead of using directly measured recipe-specific emission factors for each individual recipe or set of similar recipes.[3] This proposed modification to the calculation and monitoring requirements for the largest semiconductor manufacturing facilities would not change any of the other provisions in Subpart I that semiconductor manufacturing facilities are required to follow for calculating GHG emissions. Further, EPA is proposing to provide flexibility for a limited time while the Agency continues to explore and evaluate industry's concerns with Subpart I and considers alternative methods that are being proposed by the industry as discussed in more detail in paragraphs below.

The proposed change in 40 CFR 98.93(a)(2)(ii) to the method used by the largest semiconductor manufacturing facilities would not affect the number of facilities that report, and would not affect the GHG emissions that are covered by the Subpart I reporting requirements. It would provide greater flexibility to the largest facilities in the initial two years of implementation of Subpart I. Under this proposal, beginning in the 2013 reporting year, the largest facilities would be required to use recipe-specific utilization and by-product formation rates as specified in 40 CFR 98.93(a)(2)(ii)(A).

Pursuant to provisions in Subpart I, any semiconductor manufacturing facility subject to Subpart I may use and/or request to use BAMM (40 CFR 98.94(a)). Under the BAMM provisions in Subpart I, any owner and operator that uses BAMM must follow the calculation methodologies and equations in Subpart I (40 CFR 98.93), but may use BAMM for specific parameters and for a specific time period for which it is approved. EPA included this flexibility in the final rule for those facilities that are unable to meet the monitoring and/or QA/QC provisions in Subpart I by January 1, 2011.

EPA believes that the changes being proposed today to the calculation methodologies for the largest semiconductor manufacturing facilities are preferable to relying on the BAMM process to address concerns with the recipe-specific emission factors for the plasma etching process type during 2011 and 2012. First, adopting these changes would reduce burden for such facilities and for EPA. In other words, rather than requiring each owner and operator to prepare and submit a BAMM request to EPA to use BAMM for the directly measured recipe-specific emission factors, EPA is proposing to allow those facilities to use default emission factors during the initial years of compliance. Second, it would make transparent the methodology that would apply to the largest facilities in 2011 and 2012, which would not necessarily occur if each facility were using their own facility-specific BAMM.

This proposed change would apply only for 2011 and 2012. During this time, EPA will continue to better understand and evaluate industry's concerns with Subpart I. In addition, EPA will also consider alternatives to the use of recipe-specific emission factors by the largest facilities that have been proposed by the industry.

In a letter dated May 26, 2011 (available in docket EPA–HQ–OAR–2009–0927), SIA identified the following three alternatives that they are proposing and for which they are currently collecting information to support their development: (1) Etch Process Subcategories and Default Emissions Factors; (2) Direct Estimation of Emissions Based on Use Allocation and Application of Abatement Unit Destruction Efficiency (DRE); and, (3) Stack Testing. For more information on the three options, please refer to SIA's letter (available in docket EPA–HQ–OAR–2009–0927).

As stated in their letter, ''SIA and its member companies, in collaboration with technical support from the International Sematech Manufacturing Initiative (ISMI), are implementing a workplan under a robust schedule to collect and analyze data on each proposed alternative.'' SIA noted that they plan to submit information to EPA, including data and analyses, on the proposed alternatives beginning in June 2011, July 2011, and September 2011, depending on the alternative.

[1] 74 FR 16448 (April 10, 2009) and 74 FR 56260 (October 30, 2009). Response to Comments Documents can be found at *http://www.epa.gov/climatechange/emissions/responses.html*.

[2] The ''largest'' semiconductor manufacturing facilities are defined as those facilities that fabricate devices on wafers measuring 300 mm or less in diameter and that have an annual manufacturing capacity of greater than 10,500 m^2 of substrate.

[3] Pursuant to Subpart I, to be included in a set of similar recipes, a recipe must be similar to the recipe in the set for which recipe-specific utilization and by-product formation rates have been measured.

After SIA provides EPA with initial data to support the development of the three alternatives, EPA plans to undertake comprehensive analyses to evaluate whether the methodologies meet EPA's stated goals. One of those goals is to gather facility-level emissions estimates for the largest semiconductor manufacturing facilities that are more precise and accurate than the estimates developed using the method that is required for the other semiconductor facilities, thereby ensuring the level of rigor is commensurate with potential to emit. While EPA is open to evaluating the three options that SIA has proposed, at this time, EPA has not made any decisions about which alternatives may be included in a subsequent action.

EPA requests comment on whether to extend the use of the default emission factors for the plasma etching process type for the largest semiconductor facilities beyond December 31, 2012. More specifically, EPA is requesting comment on whether to allow the largest semiconductor manufacturing facilities to use the method required for the other semiconductor manufacturing facilities for an additional year until December 31, 2013. EPA is requesting comment on this extension in the event that the Agency determines that additional time would be necessary to develop and promulgate one or more alternative methodologies for the largest semiconductor manufacturing facilities that continue to have concerns with the recipe-specific measurement approach. While it is EPA's goal to finalize a revision to Subpart I that would allow the largest semiconductor manufacturing facilities to implement one or more alternative methodologies on January 1, 2013, EPA is considering whether additional time may be necessary given the technical complexities associated with the development of alternatives.

In a separate action also published in today's **Federal Register**, EPA is extending three of the deadlines contained in the Subpart I BAMM provisions that relate to when owners and operators may use or request to use BAMM from June 30, 2011 to September 30, 2011. As EPA explains in the preamble to that action, extending the dates by which owners and operators may use and/or request to use BAMM will allow EPA additional time to consider comments and take final action on this proposal to allow the largest semiconductor manufacturing facilities to use default emission factors for the plasma etching process type during the initial years of implementation. In addition, the extension allows owners and operators of affected facilities additional time to assess their facilities to determine if it will be necessary for them to apply for BAMM for any other aspect of Subpart I beyond 2011 for unique and extreme circumstances. For more information, please refer to the preamble to the final rule, *Mandatory Reporting of Greenhouse Gases: Additional Sources of Fluorinated GHGs: Extension of Best Available Monitoring Provisions for Electronics Manufacturing.*

B. Subpart I BAMM Provisions

In this notice, EPA is requesting comment on whether to extend until December 31, 2011 the period during which an owner or operator subject to Subpart I may, without submitting a petition, use BAMM to estimate 2011 emissions. Pursuant to the final rule published today, to estimate emissions that occur from January 1, 2011 to September 30, 2011, owners and operators may use BAMM without submitting a request for approval to the EPA Administrator. This means that starting October 1, 2011, owners and operators subject to Subpart I must discontinue using BAMM and begin following all applicable monitoring and QA/QC requirements of Subpart I unless they have submitted a request and received an approval from the Administrator to use BAMM to estimate emissions beyond September 30, 2011. EPA is requesting comment on whether to extend the date by which owners and operators may use BAMM without submitting a request for approval by the Administrator to December 31, 2011. Under this approach, owners and operators could use BAMM without submitting a request for approval by the Administrator to estimate emissions that occur from January 1, 2011 to December 31, 2011. Starting January 1, 2012, owners and operators subject to Subpart I would have to discontinue using BAMM unless a request to use BAMM beyond December 31, 2011 were approved by the Administrator. This extension would provide flexibility for any facility that was unable to meet the February 28, 2011 deadline for submitting a request for extension in the use of BAMM in 2011 for parameters other than recipe-specific emission factors. We are considering this flexibility in light of the short period of time between publication of the rule and the February 28, 2011 deadline.

EPA is also requesting comment on whether to extend the other two relevant BAMM deadlines by which an owner or operator may request the use of BAMM for recipe-specific emission factors in 2011 and for estimating emissions beyond December 31, 2011. In the final rule published today, EPA extended two deadlines by which an owner or operator must submit a petition to the Administrator to request the use of BAMM. First, EPA extended the deadline by which an owner or operator may submit a BAMM request for approval by the Administrator for recipe-specific utilization and by-product formation rates for the plasma etching process type in 2011 from June 30, 2011 to September 30, 2011. And second, EPA extended the date by which an owner or operator may submit a request for approval by the Administrator to extend the use of BAMM beyond December 31, 2011 for unique and extreme circumstances from June 30, 2011 to September 30, 2011.

EPA believes that both of those deadlines are appropriate and that they should not be further delayed for the following reasons. First, with respect to the deadline to submit a BAMM request for recipe-specific emission factors, if today's proposal is finalized, EPA does not anticipate receiving requests for the use of BAMM for recipe-specific emission factors in 2011 because it will no longer be required for the largest facilities for 2011 and 2012. Second, for requests to use BAMM to estimate emissions beyond December 31, 2011 for unique and extreme circumstances, EPA believes that a deadline of September 30, 2011 is appropriate because sufficient time is needed for EPA to review the request and respond to the owner or operator before the beginning of the next reporting period on January 1, 2012. If today's proposed action to allow flexibility for the largest semiconductor manufacturing facilities is finalized, EPA anticipates receiving only limited requests to use BAMM to estimate emissions beyond December 31, 2011. Nevertheless, EPA requests comment on extending the deadlines by which an owner or operator may submit a request to use BAMM for recipe-specific emission factors in 2011 and for estimating emissions beyond December 31, 2011.

C. Apportioning Model Verification

EPA is requesting comment on the issue raised in SIA's Petition for Reconsideration with regard to the verification requirement for facility-specific engineering models used to apportion gas consumption. Pursuant to 40 CFR 98.94(c)(2), a facility must demonstrate that the difference between the actual and modeled gas consumption for the gas used in the largest quantity on a mass basis for the plasma etching process type is less than or equal to 5 percent.

In the 2010 proposed rule (75 FR 18652), EPA proposed to require electronics manufacturing facilities to apportion consumption of each fluorinated GHG used at a facility across process categories in which that gas was used based on the quantifiable indicator of number of wafer passes. EPA also requested comment, including background information, on what quantifiable indicators other than wafer passes might be appropriately used to apportion consumption. In response to the proposed rule, commenters argued that using a facility-specific engineering model based on wafer passes was overly burdensome and not currently feasible. Some commenters suggested more flexible methods in which the apportioning was based on at least one quantifiable indicator and engineering knowledge. Commenters also asserted that EPA should not prescribe specific quantifiable indicators for apportioning gas consumption in the final rule.

In response to the comments on the proposed wafer pass-based apportioning model, EPA revised the requirements for gas apportioning models in the final 2010 rule (FR 74774) to provide flexibility to facilities. Unlike the proposal, the final rule does not specify the quantifiable metric that must be used in apportioning models; reporters are allowed to select the quantifiable metric(s) on which to base their facility-specific engineering model. Because EPA provided for flexibility in the final rule, EPA included a verification process to ensure consistency among reporting entities. This is because facilities will use different models and information to apportion gas consumption and calculate emissions, and because a minimum level of certainty and accuracy must be maintained across reporting facilities.

We view the verification requirement in the final rule (40 CFR 98.94(c)(2)) as a logical outgrowth of the proposal. In the final rule, EPA balanced the need for flexibility with the need for accuracy in the consumption estimate. Nonetheless, we would like Petitioners and others to have the opportunity to comment on the approach adopted in the final rule and to provide additional information they believe to be relevant. For these reasons, we request public comment on this approach. We will consider these comments and evaluate whether changes are warranted, including whether to propose an alternative approach in a subsequent action.

Specifically, we request comment on whether the requirement to meet the 5 percent verification standard is overly burdensome, and if so, why. To support this explanation, we request detailed information and facility-specific examples. We also request comment on whether existing equipment or instruments (*e.g.,* mass flow controllers already installed and used on every process tool) can be used to measure actual gas consumption for the purposes of model verification, and the associated costs of using that equipment or instrumentation. If these costs vary from facility to facility, we request comment on the range of costs across facilities and the approximate numbers of facilities that would incur the various costs. In addition, we request comment on the specific actions or modifications a facility would have to take to comply with the requirement and the associated costs (*e.g.,* install new software for mass flow controllers, purchase and install flow meters or scales, *etc.*). Where these actions or modifications vary from facility to facility, we request comment on the range across facilities, and the approximate number of facilities that would have to take particular actions or modifications. Lastly, we request comment on other approaches that could be used to verify modeled gas consumption to a similar level of accuracy as the current requirement (*i.e.,* whether verification could be accomplished through other means). Note that those approaches should not be based on subjective information (*e.g.,* engineering judgment).

In today's notice, EPA is not taking any other action on other issues raised by SIA in their Petition for Reconsideration. EPA recognizes that the Petition raises other issues. Although EPA is aware of these concerns, we are not proposing changes relating to those concerns in this action, and we are not seeking comment on those issues at this time. EPA reserves the right to further consider those issues at a later time. EPA is also taking no action at this time on issues raised by 3M Company in their January 28, 2011 Petition for Reconsideration of Subpart I.

III. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This action does not impose any new information collection burden. These proposed amendments do not make any substantive changes to the reporting requirements in the subpart for which amendments are being proposed. The proposed amendments to the reporting requirements are expected to reduce the reporting burden by allowing reporters to use default values instead of recipe-specific values for the first two reporting years (2011 and 2012). However, the Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations, 40 CFR 98 subpart I (75 FR 74774, December 1, 2010), under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0650. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act (RFA)

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

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

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives ''which minimize any significant economic impact of the rule

on small entities.'' 5 U.S.C. 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. The proposed rule amendments will reduce the burden for the largest semiconductor manufacturing facilities by providing flexibility during the initial years of compliance. The proposed action does not impose any new requirements on regulated entities.

We continue to be interested in the potential impacts of the proposed rule amendments on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act (UMRA)

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538, requires Federal agencies, unless otherwise prohibited by law, to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Federal agencies must also develop a plan to provide notice to small governments that might be significantly or uniquely affected by any regulatory requirements. The plan must enable officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates and must inform, educate, and advise small governments on compliance with the regulatory requirements.

The proposed rule amendments do not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. Thus, the proposed rule amendments are not subject to the requirements of section 202 and 205 of the UMRA. This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. The proposed amendments will not impose any new requirements for 40 CFR part 98, and the rule amendments would not unfairly apply to small governments. Therefore, this action is not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132.

These amendments apply directly to facilities that use and emit fluorinated GHGs in the manufacture of certain electronic devices. They do not apply to governmental entities because no government facilities would be affected. This regulation also does not limit the power of States or localities to collect GHG data and/or regulate GHG emissions. Thus, Executive Order 13132 does not apply to this action.

Although section 6 of Executive Order 13132 does not apply to this action, EPA did consult with State and local officials or representatives of State and local governments during the development of the Mandatory Reporting Rule. A summary of EPA's consultations with State and local governments is provided in Section VIII.E of the preamble to the 2009 final rule.

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 this proposed action from State and local officials.

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

This action does not have Tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). The proposed rule amendments would not result in any changes to the requirements that are not currently required for 40 CFR part 98. Thus, Executive Order 13175 does not apply to this action.

Although Executive Order 13175 does not apply to this action, EPA sought opportunities to provide information to Tribal governments and representatives during the development of the Mandatory Reporting Rule. A summary of the EPA's consultations with Tribal officials is provided in Sections VIII.D and VIII.F of the preamble to the 2009 final Mandatory Reporting Rule (74 FR 56260, October 30, 2009) and Section IV.F of the preamble to the 2010 final rule for Subpart I (75 FR 74774).

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

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

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

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

This proposed rulemaking does not involve technical standards. Any technical standards that are required under Subpart I were already included in promulgation of the final Subpart I provisions on December 1, 2011 (75 FR 74774). Therefore, EPA is not considering the use of any voluntary consensus standards in this action.

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

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

EPA has determined that this proposed rule will not have disproportionately high and adverse

human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment because it is a rule addressing information collection and reporting procedures.

List of Subjects in 40 CFR Part 98

Environmental protection, Administrative practice and procedures, Air pollution control, Monitoring, Reporting and recordkeeping.

Dated: June 15, 2011.

Lisa P. Jackson,

Administrator.

For the reasons stated in the preamble, title 40, chapter I, of the Code of Federal Regulations is proposed to be amended as follows:

PART 98—[AMENDED]

1. The authority citation for part 98 continues to read as follows:

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

Subpart I—[Amended]

2. Section 98.93 is amended by revising paragraph (a)(2)(ii) introductory text to read as follows:

§ 98.93 Calculating GHG emissions.

(a) * * *

(2) * * *

(ii) If your facility has an annual manufacturing capacity of greater than 10,500 m^2 of substrate, as calculated using Equation I–5 of this subpart, you must adhere to the procedures in paragraphs (a)(2)(ii)(A) through (a)(2)(ii)(C) of this section, except that you may use the procedures specified in paragraph (a)(2)(i) of this section for the 2011 and 2012 reporting years.

* * * * *

[FR Doc. 2011–15651 Filed 6–21–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 174 and 180

[EPA–HQ–OPP–2010–0602; FRL–8878–1]

Receipt of a Pesticide Petition Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petition and request for comment.

SUMMARY: This document announces the Agency's receipt of an initial filing of a pesticide petition requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before July 22, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–0602 and the pesticide petition number (PP), by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2010–0602 and the pesticide petition number (PP). EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Julie Chao, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001*; telephone number:* (703) 308–8735; *e-mail address: chao.julie@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

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

2. *Tips for preparing your comments. When submitting comments, remember to:*

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the agency taking?

EPA is announcing receipt of a pesticide petition filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, requesting the establishment or modification of regulations in 40 CFR part 174 or part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the request before responding to the petitioner. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petition described in this document contains data or information prescribed in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the pesticide petition. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on this pesticide petition.

Pursuant to 40 CFR 180.7(f), a summary of the petition that is the subject of this document, prepared by the petitioner, is included in a docket EPA has created for this rulemaking. The docket for this petition is available on-line at *http://www.regulations.gov.*

As specified in FFDCA section 408(d)(3), (21 U.S.C. 346a(d)(3)), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

Notice of the Agency's receipt of the following petition was previously announced in the **Federal Register** of August 11, 2010 (75 FR 48667) (FRL–8840–6), however, the petition document was not made available in the docket. Therefore, EPA is republishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities.

PP 0F7734. Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27410, proposes to establish a tolerance in 40 CFR part 180 for residues of the insecticide thiamethoxam, (3-[(2-chloro-5-thiazolyl) methyl]tetrahydro-5-methyl-*N*-nitro-4*H*-1,3,5-oxadiazin-4-imine) and its metabolite [*N*-(2-chloro-thiazol-5-ylmethyl)-*N'*-methyl-*N'*-nitroguanidine], in or on food commodities/feed commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments at 0.01 part per million (ppm). Syngenta Crop Protection has submitted practical analytical methodology for detecting and measuring levels of thiamethoxam in or on raw agricultural commodities. This method is based on crop specific cleanup procedures and determination by liquid chromatography with either ultraviolet (UV) or mass spectrometry (MS) detections. The limit of detection (LOD) for each analyte of this method is 1.25 nanogram (ng) injected for samples analyzed by UV and 0.25 ng injected for samples analyzed by MS, and the limit of quantification (LOQ) is 0.005 ppm for milk and juices, and 0.01 ppm for all other substrates.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 7, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2011–15267 Filed 6–21–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 262

[EPA–HQ–RCRA–2001–0032; FRL–9321–7]

Hazardous Waste Manifest Printing Specifications Correction Rule

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing a minor change to the Resource Conservation and Recovery Act (RCRA) hazardous waste manifest regulations that affects those entities that print the hazardous waste manifest form in accordance with EPA's specifications. Specifically, this action proposes to amend the current printing specification regulation to indicate that red ink, as well as other distinct colors, or other methods to distinguish the copy distribution notations from the rest of the printed form and data entries are permissible. This proposed change would afford authorized manifest form printers

greater flexibility in complying with the Federal hazardous waste manifest printing specifications.

DATES: Written comments must be received by July 22, 2011.

ADDRESSES: Submit your comments identified by Docket ID No. EPA–HQ–RCRA–2001–0032 by one of the following methods:

- *http://www.regulations.gov:* follow the on-line instructions for submitting comments.
- *E-mail: RCRA docket@EPA.gov* and *groce.bryan@epa.gov* or *lashier.rich@epa.gov.* Attention Docket ID No. EPA–HQ–RCRA–2001–0032.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–RCRA–2001–0032.
- *Mail:* RCRA Docket (28221T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Attention Docket ID No. EPA–HQ–RCRA–2001–0032. Please include a total of two copies of your comments.
- *Hand Delivery:* Please deliver two copies to the EPA Docket Center, EPA West Building, Room 3334, 1301 Connecticut Ave., NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–RCRA–2001–0032. EPA's policy is that all comments received will be included in the public docket without change and be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are within 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 HQ–Docket Center, Docket ID No. EPA–HQ–RCRA–2001–0032, EPA West Building, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the RCRA Docket is (202) 566–0270. A reasonable fee may be charged for copying docket materials.

FOR FURTHER INFORMATION CONTACT: For more information on this rulemaking, contact Bryan Groce or Richard LaShier, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (MC: 5304P), 1200 Pennsylvania Ave., NW., Washington, DC 20460; *Phone for Bryan Groce:* (703) 308–8750, *Phone for Richard LaShier:* (703) 308- 8796; or *e-mail: groce.bryan@epa.gov,* or *lashier.rich@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Why is EPA issuing this proposed rule?

EPA is proposing a minor amendment that would change the Federal printing specifications applicable to those entities that print the hazardous waste manifest form. This proposed rule would change only the printing specification in 40 CFR 262.21(f)(4) that currently requires that certain copy distribution notations appearing in the margins of the form must be printed only in red ink. In the ''Rules and Regulations'' section of this **Federal Register**, EPA is making this change as a Direct Final rule without a prior proposed rule, because we view this as a non-controversial action and anticipate no adverse comment. We have explained our reasons for this proposed action in the preamble to the Direct Final rule. If we receive no adverse comment on this minor change we are publishing today, we will not take further action on this proposed rule. If, however, we receive adverse comment, we will publish a timely withdrawal in the **Federal Register** to notify the public that the regulatory amendment in the Direct Final rule will not take effect, and the reasons for such a withdrawal. If the Direct Final rule in the Rules and Regulations section of this **Federal Register** is withdrawn, all comments will be addressed in a subsequent final action on the proposed rule. We do not intend to institute a second comment period on this action. Any parties interested in commenting must do so at this time.

The regulatory text for this proposal is identical to that for the Direct Final rule published in the Rules and Regulations section of this **Federal Register**. For further information, please see the information provided in the **ADDRESSES** section of this **Federal Register**.

II. Does this action apply to me?

Entities potentially affected by this action are the hazardous waste manifest printers subject to 40 CFR 262.21(f) of the RCRA hazardous waste regulations. States are not affected by the changes to the printing specifications unless they should opt to print manifests. No states are currently printing these forms.

III. Statutory and Executive Order Reviews

For a complete discussion of all the administrative requirements applicable to this action, see the discussion in the ''Statutory and Executive Order Reviews'' section to the preamble for the Direct Final rule that is published in the Rules and Regulations section of this **Federal Register**.

A. Regulatory Flexibility Act.

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, a small entity is defined as: (1) A small business as defined by the Small Business

Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's Direct Final rule on small entities, I certify that this proposed rule will not have a significant economic impact on a substantial number of small entities. This action proposes only a minor change to the manifest printing specifications, and the effect of this proposed change would make it easier for printers to comply with the manifest printing specification by providing additional options. Therefore, this proposed rule would not impose any new burden or costs on printers or users of the manifest, including printers and users who are small entities as defined by the RFA. Since the rule would not have any significant adverse economic impact on small entities, the RFA does not require EPA to perform a regulatory flexibility analysis.

List of Subjects in 40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

Dated: June 15, 2011.

Mathy Stanislaus,

Assistant Administrator, Office of Solid Waste & Emergency Response.

[FR Doc. 2011–15645 Filed 6–21–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF LABOR

Office of Federal Contract Compliance Programs

41 CFR Parts 60–250 and 60–300

RIN 1250–AA00

Affirmative Action and Nondiscrimination Obligations of Contractors and Subcontractors Regarding Protected Veterans

AGENCY: Office of Federal Contract Compliance Programs, Labor.

ACTION: Notice of proposed rulemaking and extension of comment period.

SUMMARY: On April 26, 2011, the Office of Federal Contract Compliance Programs (OFCCP) published a **Federal Register** notice of proposed rulemaking (NPRM). This NPRM proposes revising regulations implementing the affirmative action provisions of the Vietnam Era Veterans' Readjustment Assistance Act of 1974, as amended. This document extends the comment period for the proposed rule for fourteen (14) days. If you have already commented on the proposed rule you do not need to resubmit your comment. OFCCP will consider all comments received from the date of publication of the proposed rule through the close of the extended comment period.

DATES: The comment period for the NPRM published on April 26, 2011 (76 FR 23358), scheduled to close on June 27, 2011, is extended until July 11, 2011.

ADDRESSES: You may submit comments, identified by RIN 1250–AA00, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 693–1304 (for comments of six pages or fewer).
- *Mail:* Debra A. Carr, Director, Division of Policy, Planning, and Program Development, Office of Federal Contract Compliance Programs, Room C–3325, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Debra A. Carr, Director, Division of Policy, Planning, and Program Development, Office of Federal Contract Compliance Programs, Room C–3325, 200 Constitution Avenue, NW., Washington, DC 20210.

SUPPLEMENTARY INFORMATION: On April 26, 2011, OFCCP published a proposed rule entitled ''Affirmative Action and Nondiscrimination Obligations of Contractors and Subcontractors Regarding Protected Veterans'' (76 FR 23358). OFCCP was to receive comments on this NPRM on or before June 27, 2011.

Various organizations submitted requests to extend the comment period by an additional sixty (60) days or more. We considered these requests and determined that it is appropriate to provide an additional 14-day period for comment on the proposed regulation. We are, therefore, extending the comment period until Monday, July 11, 2011.

Extension of Comment Period

OFCCP determined that the public could use additional time to review the potential impact of the proposed requirements. Therefore, to allow the public sufficient time to review and comment on the NPRM, OFCCP is extending the comment period until July 11, 2011.

Signed at Washington, DC, this 17th day of June 2011.

Patricia Shiu,

Director, Office of Federal Contract Compliance Programs.

[FR Doc. 2011–15646 Filed 6–21–11; 8:45 am]

BILLING CODE 4510–45–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA–2011–0002; Internal Agency Docket No. FEMA–B–1198]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed rule.

SUMMARY: Comments are requested on the proposed Base (1% annual-chance) Flood Elevations (BFEs) and proposed BFE modifications for the communities listed in the table below. The purpose of this proposed rule is to seek general information and comment regarding the proposed regulatory flood elevations for the reach described by the downstream and upstream locations in the table below. The BFEs and modified BFEs are a part of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, these elevations, once finalized, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents in those buildings.

DATES: Comments are to be submitted on or before September 20, 2011.

ADDRESSES: The corresponding preliminary Flood Insurance Rate Map (FIRM) for the proposed BFEs for each community is available for inspection at the community's map repository. The respective addresses are listed in the table below.

You may submit comments, identified by Docket No. FEMA–B–1198, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472,

(202) 646–4064, or (e-mail) *luis.rodriguez1@dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–4064, or (e-mail) *luis.rodriguez1@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) proposes to make determinations of BFEs and modified BFEs for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed BFEs and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in those buildings.

Comments on any aspect of the Flood Insurance Study and FIRM, other than the proposed BFEs, will be considered. A letter acknowledging receipt of any comments will not be sent.

National Environmental Policy Act. This proposed rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

Executive Order 12866, Regulatory Planning and Review. This proposed rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866, as amended.

Executive Order 13132, Federalism. This proposed rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This proposed rule meets the applicable standards of Executive Order 12988.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is proposed to be amended as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.4 [Amended]

2. The tables published under the authority of § 67.4 are proposed to be amended as follows:

State	City/town/county	Source of flooding	Location **	*Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL)	
				Existing	Modified
City of Colonial Heights, Virginia					
Virginia	City of Colonial Heights.	Old Town Creek	Approximately 0.63 mile downstream of Conduit Road.	+10	+11
			Approximately 0.48 mile upstream of the railroad.	+67	+68

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.
** BFEs to be changed include the listed downstream and upstream BFEs, and include BFEs located on the stream reach between the referenced locations above. Please refer to the revised Flood Insurance Rate Map located at the community map repository (see below) for exact locations of all BFEs to be changed.

Send comments to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472.

ADDRESSES

City of Colonial Heights

Maps are available for inspection at 202 James Avenue, Colonial Heights, VA 23834.

Unincorporated Areas of Halifax County, North Carolina					
North Carolina	Unincorporated Areas of Halifax County.	Fishing Creek	Approximately 1.1 miles upstream of the Fishing Creek Tributary 2 confluence.	+60	+59
			Approximately 50 feet downstream of White Oak Road.	+129	+132

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.

State	City/town/county	Source of flooding	Location **	*Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL)	
				Existing	Modified

∧ Mean Sea Level, rounded to the nearest 0.1 meter.

** BFEs to be changed include the listed downstream and upstream BFEs, and include BFEs located on the stream reach between the referenced locations above. Please refer to the revised Flood Insurance Rate Map located at the community map repository (see below) for exact locations of all BFEs to be changed.

Send comments to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472.

ADDRESSES

Unincorporated Areas of Halifax County

Maps are available for inspection at the Halifax County Office, 15 West Pittsylvania Street, Halifax, NC 27839.

Flooding source(s)	Location of referenced elevation **	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL)		Communities affected
		Effective	Modified	
Osceola County, Florida, and Incorporated Areas				
Bass Slough (Lower Reach)	Approximately 1,211 feet downstream of County Route 525.	None	+57	City of Kissimmee, Unincorporated Areas of Osceola County.
	Approximately 0.6 mile upstream of State Route 530	None	+76	
Bass Slough (Upper Reach)	Approximately 1,863 feet downstream of the Bass Slough Tributary confluence.	None	+79	City of Kissimmee, Unincorporated Areas of Osceola County.
	Approximately 337 feet upstream of Florida Parkway	None	+80	
Bass Slough Tributary	At the Bass Slough (Upper Reach) confluence	None	+79	Unincorporated Areas of Osceola County.
	Approximately 0.4 mile upstream of the Bass Slough (Upper Reach) confluence.	None	+79	
Clay Hole Pond	Entire shoreline	None	+66	Unincorporated Areas of Osceola County.
Courthouse Pond	Entire shoreline	None	+68	Unincorporated Areas of Osceola County.
Eagle Pond	Entire shoreline	None	+65	Unincorporated Areas of Osceola County.
East City Canal Tributary 1	At the upstream side of Vine Street	+65	+66	City of Kissimmee.
	Approximately 637 feet upstream of Vine Street	+65	+66	
Lake Marian	Entire shoreline	None	+59	Unincorporated Areas of Osceola County.
Multiple Ponding Areas	Area bound by San Remo Road to the north and east, Cypress Parkway to the south, and Marigold Avenue to the west.	None	+69	Unincorporated Areas of Osceola County.
Multiple Ponding Areas	Area bound by Florida's Turnpike to the north and east and State Route 523 to the south and west.	None	+65	City of Kissimmee.
Multiple Ponding Areas	Area approximately 0.8 mile northwest of the intersection of Brandon Lane and County Route 523, bound by Williams Road to the north, U.S. Route 441 to the east, and Florida's Turnpike to the south and west.	None	+69	Unincorporated Areas of Osceola County.
Multiple Ponding Areas	Area bound by County Route 523 to the north, U.S. Route 441 to the east, Hayman Ranch Road to the south, and Florida's Turnpike to the west.	None	+69	Unincorporated Areas of Osceola County.
Multiple Ponding Areas	Area approximately 2.4 miles north of the intersection of 3rd Street and 4th Avenue, bound by Williams Road to the north, U.S. Route 441 to the east, and Florida's Turnpike to the south and west.	None	+67	Unincorporated Areas of Osceola County.
Otter Pond	Entire shoreline	None	+69	Unincorporated Areas of Osceola County.

Flooding source(s)	Location of referenced elevation **	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL)		Communities affected
		Effective	Modified	
Ponding Area	Area bound by West Orange Street to the north, North Main Street to the east, Sumner Street to the south, and U.S. Routes 17/92 to the west.	+65	+66	Unincorporated Areas of Osceola County.
Ponding Area	Area bound by Pleasant Hill Road to the north, Florida's Turnpike to the east, and Scrub Jay Trail to the south and west.	None	+64	Unincorporated Areas of Osceola County.
Ponding Area	Area approximately 0.9 mile east of the intersection of Martigues Drive and Amiens Road, bound by West Southport Road to the north, Florida's Turnpike to the east, and Scrub Jay Trail to the south and west.	None	+63	Unincorporated Areas of Osceola County.
Ponding Area	Area bound by Amiens Road to the north and east, Chestnut Street to the south, and Bordeaux Road to the west.	None	+62	Unincorporated Areas of Osceola County.
Ponding Area	Area approximately 0.6 mile east of the intersection of Saint Michel Way and Amiens Road, bound by West Southport Road to the north, Florida's Turnpike to the east, and Scrub Jay Trail to the south and west.	None	+62	Unincorporated Areas of Osceola County.
Ponding Area	Area bound by Old Pleasant Hill Road to the north, Scrub Jay Trail to the east, and the Polk County boundary to the south and west.	None	+60	Unincorporated Areas of Osceola County.
Ponding Area	Area bound by Chestnut Street to the north, Scrub Jay Trail to the east, and the Polk County boundary to the south and west.	None	+63	Unincorporated Areas of Osceola County.
Ponding Area	Area approximately 2.2 miles north of the intersection of Coulter Drive and County Route 523, bound by Williams Road to the north, U.S. Route 441 to the east, and Florida's Turnpike to the south and west.	None	+66	Unincorporated Areas of Osceola County/
Unnamed Connecting Channel downstream of Clay Hole Pond.	Just upstream of Eagle Pond	None	+65	Unincorporated Areas of Osceola County/
	Just downstream of Clay Hole Pond	None	+66	
Unnamed Connecting Channel downstream of Eagle Pond.	Approximately 0.6 mile downstream of Eagle Pond	None	+65	Unincorporated Areas of Osceola County.
	Just downstream of Eagle Pond	None	+65	
Unnamed Connecting Channel upstream of Lake Marian.	Just upstream of Lake Marian	None	+59	Unincorporated Areas of Osceola County.
	Approximately 0.4 mile upstream of Lake Marian	None	+65	
Unnamed Connecting Channel upstream of Lake Marian.	Just upstream of Lake Marian	None	+59	Unincorporated Areas of Osceola County.
	Approximately 1.0 mile upstream of Lake Marian	None	+69	
Unnamed Flooding Area upstream of Lake Marian.	Just upstream of Lake Marian	None	+59	Unincorporated Areas of Osceola County.
	Approximately 0.5 mile upstream of Lake Marian	None	+65	
WPA Canal Tributary 1	Approximately 1,612 feet upstream of the WPA Canal confluence.	None	+71	City of St. Cloud, Unincorporated Areas of Osceola County.
	Approximately 1.6 miles upstream of Snail Kite Avenue.	None	+75	
WPA Canal Tributary 1–1	At the WPA Canal Tributary 1 confluence	None	+75	City of St. Cloud, Unincorporated Areas of Osceola County.
	Approximately 0.7 mile upstream of the WPA Canal Tributary 1 confluence.	None	+75	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.
** BFEs to be changed include the listed downstream and upstream BFEs, and include BFEs located on the stream reach between the referenced locations above. Please refer to the revised Flood Insurance Rate Map located at the community map repository (see below) for exact locations of all BFEs to be changed.

Flooding source(s)	Location of referenced elevation **	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL)		Communities affected
		Effective	Modified	

Send comments to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472.

ADDRESSES

City of Kissimmee

Maps are available for inspection at City Hall, Engineering Department, Suite 301, 101 North Church Street, Kissimmee, FL 34741.

City of St. Cloud

Maps are available for inspection at City Hall, Public Works Department, Building A, 2nd Floor, 1300 9th Street, St. Cloud, FL 34769.

Unincorporated Areas of Osceola County

Maps are available for inspection at the Osceola County Stormwater Section, 1 Courthouse Square, Suite 1400, Kissimmee, FL 34741.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: June 10, 2011.

Sandra K. Knight,

Deputy Federal Insurance and Mitigation Administrator, Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2011–15620 Filed 6–21–11; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 541

[Docket No. NHTSA–2011–0075]

Preliminary Theft Data; Motor Vehicle Theft Prevention Standard

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Publication of preliminary theft data; request for comments.

SUMMARY: This document requests comments on data about passenger motor vehicle thefts that occurred in calendar year (CY) 2009 including theft rates for existing passenger motor vehicle lines manufactured in model year (MY) 2009. The preliminary theft data indicate that the vehicle theft rate for CY/MY 2009 vehicles (1.33 thefts per thousand vehicles) decreased by 21.3 percent from the theft rate for CY/MY 2008 vehicles (1.69 thefts per thousand vehicles).

Publication of these data fulfills NHTSA's statutory obligation to periodically obtain accurate and timely theft data, and publish the information for review and comment.

DATES: Comments must be submitted on or before August 22, 2011.

ADDRESSES: You may submit comments [identified by Docket No. NHTSA–2011–0075 by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the Supplementary Information section of this document. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://DocketsInfo.dot.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov,* or the street address listed above. Follow the online instructions for accessing the dockets.

FOR FURTHER INFORMATION CONTACT: Ms. Deborah Mazyck, Office of International Policy, Fuel Economy and Consumer Programs, NHTSA, 1200 New Jersey Avenue, SE., Washington, DC 20590. Ms. Mazyck's telephone number is (202) 366–4139. Her fax number is (202) 493–2990.

SUPPLEMENTARY INFORMATION: NHTSA administers a program for reducing motor vehicle theft. The central feature of this program is the Federal Motor Vehicle Theft Prevention Standard, 49 CFR part 541. The standard specifies performance requirements for inscribing or affixing vehicle identification numbers (VINs) onto certain major original equipment and replacement parts of high-theft lines of passenger motor vehicles.

The agency is required by 49 U.S.C. 33104(b)(4) to periodically obtain, from the most reliable source, accurate and timely theft data, and publish the data for review and comment. To fulfill the § 33104(b)(4) mandate, this document reports the preliminary theft data for CY 2009 the most recent calendar year for which data are available.

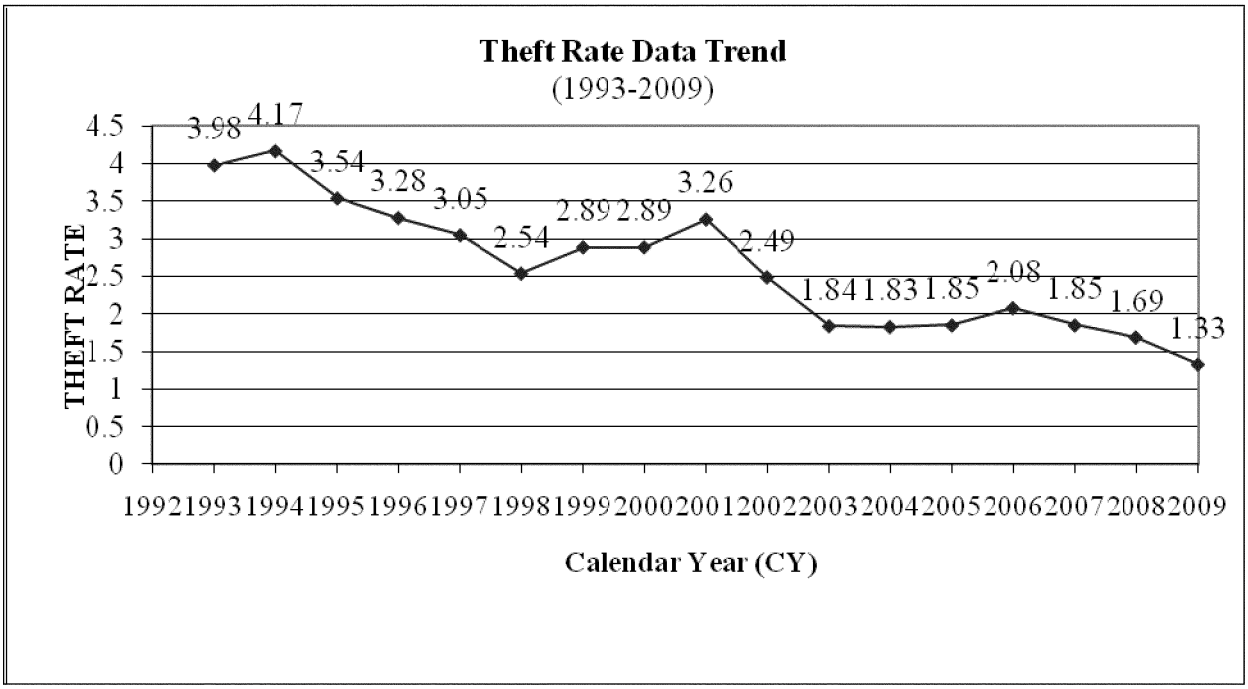
In calculating the 2009 theft rates, NHTSA followed the same procedures it has used since publication of the 1983/1984 theft rate data (50 FR 46669, November 12, 1985). The 2009 theft rate for each vehicle line was calculated by dividing the number of reported thefts of MY 2009 vehicles of that line stolen during calendar year 2009 by the total number of vehicles in that line manufactured for MY 2009, as reported to the Environmental Protection Agency (EPA). As in all previous reports, NHTSA's data were based on information provided to NHTSA by the

National Crime Information Center (NCIC) of the Federal Bureau of Investigation. The NCIC is a government system that receives vehicle theft information from approximately 23,000 criminal justice agencies and other law enforcement authorities throughout the United States. The NCIC data also include reported thefts of self-insured and uninsured vehicles, not all of which are reported to other data sources.

The preliminary 2009 theft data show a decrease in the vehicle theft rate when compared to the theft rate experienced in CY/MY 2008 (For 2008 theft data, see 76 FR 2598, January 14, 2011). The preliminary theft rate for MY 2009 passenger vehicles stolen in calendar year 2009 decreased to 1.33 thefts per thousand vehicles produced, a decrease of 21.3 percent from the rate of 1.69 thefts per thousand vehicles experienced by MY vehicles in CY 2008. For MY 2009 vehicles, out of a total of 238 vehicle lines, 10 lines had a theft rate higher than 3.5826 per thousand vehicles, the established median theft rate for MYs 1990/1991 (See 59 FR 12400, March 16, 1994). Of the 10 vehicle lines with a theft rate higher than 3.5826, 10 are passenger car lines, none are multipurpose passenger vehicle lines, and none are light-duty truck lines.

The agency believes that the theft rate reduction is a result of several factors, including vehicle parts marking; the increased use of standard antitheft devices and other advances in electronic technology (i.e., immobilizers) and theft prevention methods; increased and improved prosecution efforts by law enforcement organizations; and, increased public awareness which may have contributed to the overall reduction in vehicle thefts. The preliminary MY 2009 theft rate reduction is consistent with the general decreasing trend of theft rates over the past 17 years as indicated by Figure 1.

Figure 1: Theft Rate Data Trend (1993-2009)



Theft rate per thousand vehicles produced

In Table I, NHTSA has tentatively ranked each of the MY 2009 vehicle lines in descending order of theft rate. Public comment is sought on the accuracy of the data, including the data for the production volumes of individual vehicle lines.

Comments must not exceed 15 pages in length (49 CFR Part 553.21). Attachments may be appended to these submissions without regard to the 15 page limit. This limitation is intended to encourage commenters to detail their primary arguments in a concise fashion.

If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential business information, should be submitted to the Chief Counsel, NHTSA, at the street address given above, and two copies from which the purportedly confidential information has been deleted should be submitted to Dockets. A request for confidentiality should be accompanied by a cover letter setting forth the information specified in the agency's confidential business information regulation. 49 CFR part 512.

All comments received before the close of business on the comment closing date indicated above for this document will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Comments on this document will be available for inspection in the docket. NHTSA will continue to file relevant information as it becomes available for inspection in the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

Those persons desiring to be notified upon receipt of their comments in the rules docket should enclose a self-addressed, stamped postcard in the

envelope with their comments. Upon receiving the comments, the docket supervisor will return the postcard by mail.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://DocketsInfo.dot.gov.*

Authority: 49 U.S.C. 33101, 33102 and 33104; delegation of authority at 49 CFR 1.50.

PRELIMINARY REPORT OF THEFT RATES FOR MODEL YEAR 2009 PASSENGER MOTOR VEHICLES STOLEN IN CALENDAR YEAR 2009

	Manufacturer	Make/model (line)	Thefts 2009	Production (Mfr's) 2009	2009 Theft rate (per 1,000 vehicles produced)
1	AUDI	AUDI S8	2	227	8.8106
2	FORD MOTOR CO.	SHELBY GT	5	581	8.6059
3	BMW	M5	2	264	7.5758
4	CHRYSLER	DODGE CHARGER	432	66,856	6.4616
5	HONDA	S2000	2	357	5.6022
6	MITSUBISHI	GALANT	152	29,716	5.1151
7	CHRYSLER	300	143	31,287	4.5706
8	NISSAN	INFINITI M35/M45	27	6,243	4.3248
9	GENERAL MOTORS	CADILLAC STS	31	7,239	4.2824
10	CHRYSLER	SEBRING CONVERTIBLE	18	4,827	3.7290
11	CHRYSLER	DODGE AVENGER	107	31,667	3.3789
12	CHRYSLER	SEBRING	65	19,588	3.3184
13	AUDI	AUDI A8	6	1,810	3.3149
14	VOLVO	V70	3	996	3.0120
15	GENERAL MOTORS	PONTIAC G5	60	20,623	2.9094
16	GENERAL MOTORS	PONTIAC G6	281	99,226	2.8319
17	CHRYSLER	DODGE CALIBER	125	44,554	2.8056
18	CHRYSLER	PT CRUISER	69	24,876	2.7738
19	GENERAL MOTORS	CHEVROLET IMPALA	499	183,769	2.7154
20	NISSAN	INFINITI FX35	35	13,375	2.6168
21	CHRYSLER	DODGE CHALLENGER	53	20,526	2.5821
22	NISSAN	PATHFINDER	13	5,076	2.5611
23	BMW	M6	1	397	2.5189
24	CHRYSLER	DODGE NITRO	26	10,539	2.4670
25	NISSAN	MAXIMA	141	58,278	2.4194
26	KIA	RONDO	42	17,573	2.3900
27	MAZDA	5	53	22,248	2.3822
28	GENERAL MOTORS	CHEVROLET MALIBU	413	176,813	2.3358
29	KIA	SPECTRA	135	60,296	2.2390
30	GENERAL MOTORS	CHEVROLET COBALT	312	141,588	2.2036
31	GENERAL MOTORS	SATURN AURA	78	35,472	2.1989
32	MERCEDES–BENZ	S–CLASS	22	10,189	2.1592
33	GENERAL MOTORS	CHEVROLET HHR	172	80,781	2.1292
34	TOYOTA	SCION TC	57	27,179	2.0972
35	JAGUAR LAND ROVER	XF	27	12,953	2.0845
36	MAZDA	3	99	47,569	2.0812
37	FORD MOTOR CO.	LINCOLN TOWN CAR	24	11,596	2.0697
38	TOYOTA	AVALON	45	22,030	2.0427
39	NISSAN	350Z	1	503	1.9881
40	VOLVO	C70	8	4,027	1.9866
41	MERCEDES–BENZ	CL–CLASS	10	5,105	1.9589
42	FORD MOTOR CO.	MUSTANG	81	41,354	1.9587
43	GENERAL MOTORS	CADILLAC DTS	32	16,566	1.9317
44	MAZDA	6	76	39,504	1.9239
45	MITSUBISHI	ECLIPSE	24	12,760	1.8809
46	NISSAN	ALTIMA	410	228,101	1.7974
47	FORD MOTOR CO.	MERCURY SABLE	11	6,146	1.7898
48	GENERAL MOTORS	CADILLAC CTS	91	50,926	1.7869
49	VOLVO	S60	12	6,837	1.7552
50	TOYOTA	CAMRY/SOLARA	781	447,882	1.7438
51	TOYOTA	COROLLA	632	363,515	1.7386
52	HYUNDAI	SONATA	270	159,775	1.6899
53	GENERAL MOTORS	CHEVROLET TRAILBLAZER	22	13,022	1.6894
54	TOYOTA	4RUNNER	13	7,803	1.6660
55	BMW	6	4	2,420	1.6529
56	GENERAL MOTORS	CHEVROLET AVEO	94	58,439	1.6085
57	NISSAN	SENTRA	104	65,096	1.5976
58	FORD MOTOR CO.	FOCUS	235	148,244	1.5852
59	HYUNDAI	ACCENT	92	59,709	1.5408
60	NISSAN	VERSA	159	104,658	1.5192

PRELIMINARY REPORT OF THEFT RATES FOR MODEL YEAR 2009 PASSENGER MOTOR VEHICLES STOLEN IN CALENDAR YEAR 2009—Continued

	Manufacturer	Make/model (line)	Thefts 2009	Production (Mfr's) 2009	2009 Theft rate (per 1,000 vehicles produced)
61	MAZDA	B SERIES PICKUP	1	660	1.5152
62	CHRYSLER	DODGE JOURNEY	124	82,331	1.5061
63	KIA	RIO	61	41,036	1.4865
64	MERCEDES–BENZ	C–CLASS	86	57,872	1.4860
65	GENERAL MOTORS	CHEVROLET CORVETTE	23	15,647	1.4699
66	NISSAN	370Z	16	11,024	1.4514
67	NISSAN	XTERRA	19	13,106	1.4497
68	JAGUAR LAND ROVER	XKR	1	696	1.4368
69	FORD MOTOR CO.	MERCURY GRAND MARQUIS	30	21,102	1.4217
70	GENERAL MOTORS	PONTIAC TORRENT	13	9,403	1.3825
71	FORD MOTOR CO.	TAURUS	34	25,094	1.3549
72	CHRYSLER	JEEP COMPASS	14	10,346	1.3532
73	NISSAN	FRONTIER PICKUP	31	23,030	1.3461
74	VOLVO	S40	9	6,743	1.3347
75	AUDI	AUDI A3	5	3,761	1.3294
76	FORD MOTOR CO.	EDGE	58	44,744	1.2963
77	GENERAL MOTORS	BUICK LACROSSE/ALLURE	24	18,532	1.2951
78	TOYOTA	YARIS	93	72,826	1.2770
79	GENERAL MOTORS	GMC ENVOY	7	5,661	1.2365
80	MASERATI	QUATTROPORTE	1	817	1.2240
81	KIA	OPTIMA	43	35,610	1.2075
82	NISSAN	GT–R	3	2,505	1.1976
83	GENERAL MOTORS	SATURN VUE	47	39,342	1.1947
84	TOYOTA	LEXUS LS	11	9,418	1.1680
85	CHRYSLER	JEEP LIBERTY	36	31,272	1.1512
86	GENERAL MOTORS	BUICK LUCERNE	36	31,751	1.1338
87	KIA	SEDONA VAN	21	18,684	1.1240
88	KIA	AMANTI	1	931	1.0741
89	TOYOTA	LEXUS IS	34	31,875	1.0667
90	TOYOTA	SCION XB	39	37,039	1.0529
91	FORD MOTOR CO.	FLEX	44	42,100	1.0451
92	GENERAL MOTORS	PONTIAC VIBE	59	56,730	1.0400
93	MAZDA	RX–8	3	3,000	1.0000
94	VOLKSWAGEN	GOLF/RABBIT/GTI	19	19,005	0.9997
95	AUDI	AUDI R8	1	1,022	0.9785
96	KIA	SORENTO	12	12,435	0.9650
97	AUDI	AUDI S4/S5	3	3,112	0.9640
98	MITSUBISHI	LANCER	37	38,655	0.9572
99	TOYOTA	SIENNA VAN	61	63,797	0.9562
100	KIA	SPORTAGE	34	35,892	0.9473
101	HONDA	ACCORD	297	315,205	0.9422
102	GENERAL MOTORS	PONTIAC G8	24	25,556	0.9391
103	HONDA	ACURA TSX	35	37,306	0.9382
104	FORD MOTOR CO.	FUSION	96	103,268	0.9296
105	TOYOTA	MATRIX	54	58,240	0.9272
106	SUZUKI	SX4	23	24,859	0.9252
107	GENERAL MOTORS	CHEVROLET EQUINOX	30	32,555	0.9215
108	MERCEDES–BENZ	E–CLASS	17	18,803	0.9041
109	MASERATI	GRANTURISMO	1	1,123	0.8905
110	NISSAN	MURANO	96	108,188	0.8873
111	CHRYSLER	JEEP WRANGLER	58	67,122	0.8641
112	VOLKSWAGEN	JETTA/GLI	97	112,506	0.8622
113	NISSAN	QUEST VAN	7	8,232	0.8503
114	FORD MOTOR CO.	LINCOLN MKS	22	26,153	0.8412
115	NISSAN	INFINITI G37	42	50,524	0.8313
116	BMW	M3	3	3,642	0.8237
117	VOLVO	C30	3	3,693	0.8123
118	SUBARU	LEGACY	21	26,278	0.7991
119	SUBARU	IMPREZA	34	42,551	0.7990
120	HYUNDAI	ELANTRA	61	76,637	0.7960
121	MERCEDES–BENZ	SL–CLASS	6	7,559	0.7938
122	TOYOTA	TACOMA PICKUP	92	116,059	0.7927
123	HONDA	CIVIC	218	278,426	0.7830
124	HYUNDAI	GENESIS	15	19,504	0.7691
125	AUDI	AUDI Q5	5	6,531	0.7656
126	FORD MOTOR CO.	ESCAPE	113	148,860	0.7591
127	MERCEDES–BENZ	SLK–CLASS	3	3,987	0.7524

PRELIMINARY REPORT OF THEFT RATES FOR MODEL YEAR 2009 PASSENGER MOTOR VEHICLES STOLEN IN CALENDAR YEAR 2009—Continued

	Manufacturer	Make/model (line)	Thefts 2009	Production (Mfr's) 2009	2009 Theft rate (per 1,000 vehicles produced)
128	HYUNDAI	SANTA FE	57	77,857	0.7321
129	MAZDA	CX–9	10	14,024	0.7131
130	GENERAL MOTORS	CHEVROLET COLORADO PICKUP	20	28,286	0.7071
131	CHRYSLER	JEEP PATRIOT	23	32,611	0.7053
132	HONDA	ACURA RDX	6	8,690	0.6904
133	FORD MOTOR CO.	LINCOLN MKX	8	11,626	0.6881
134	PORSCHE	BOXSTER	1	1,460	0.6849
135	VOLVO	S80	5	7,409	0.6749
136	AUDI	AUDI TT	2	2,989	0.6691
137	NISSAN	INFINITI FX50	1	1,510	0.6623
138	TOYOTA	RAV4	79	119,381	0.6617
139	BMW	7	5	7,613	0.6568
140	TOYOTA	LEXUS RX	42	64,266	0.6535
141	NISSAN	ROGUE	47	73,877	0.6362
142	VOLKSWAGEN	TIGUAN	12	19,076	0.6291
143	PORSCHE	CAYMAN	1	1,591	0.6285
144	TOYOTA	FJ CRUISER	2	3,185	0.6279
145	MAZDA	CX–7	8	12,906	0.6199
146	SUZUKI	VITARA/GRAND VITARA	4	6,476	0.6177
147	AUDI	AUDI A4/A5	27	44,950	0.6007
148	HONDA	ACURA 3.2 TL	20	33,690	0.5936
149	TOYOTA	HIGHLANDER	33	57,166	0.5773
150	FORD MOTOR CO.	TAURUS X	3	5,209	0.5759
151	TOYOTA	SCION XD	10	17,587	0.5686
152	MERCEDES–BENZ	SMART FORTWO	8	14,169	0.5646
153	TOYOTA	LEXUS GS	3	5,537	0.5418
154	VOLKSWAGEN	EOS	5	9,560	0.5230
155	BMW	3	44	84,350	0.5216
156	VOLKSWAGEN	PASSAT	16	31,310	0.5110
157	GENERAL MOTORS	SATURN SKY	2	4,078	0.4904
158	FORD MOTOR CO.	LINCOLN MKZ	8	16,676	0.4797
159	AUDI	AUDI A6	2	4,193	0.4770
160	GENERAL MOTORS	PONTIAC SOLSTICE	2	4,202	0.4760
161	HONDA	PILOT	40	84,089	0.4757
162	GENERAL MOTORS	GMC CANYON PICKUP	4	8,614	0.4644
163	HONDA	ACURA MDX	16	34,540	0.4632
164	HYUNDAI	TUCSON	5	11,032	0.4532
165	VOLKSWAGEN	NEW BEETLE	8	18,284	0.4375
166	MAZDA	TRIBUTE	2	4,670	0.4283
167	BMW	5	9	21,963	0.4098
168	HONDA	ODYSSEY VAN	30	73,777	0.4066
169	BMW	1	4	10,189	0.3926
170	FORD MOTOR CO.	RANGER PICKUP	19	49,466	0.3841
171	SUBARU	FORESTER	34	88,771	0.3830
172	PORSCHE	911	3	7,929	0.3784
173	FORD MOTOR CO.	MERCURY MILAN	7	18,556	0.3772
174	HONDA	ACURA 3.5 RL	1	2,670	0.3745
175	BMW	X3	2	5,448	0.3671
176	HONDA	ELEMENT	4	11,114	0.3599
177	MITSUBISHI	OUTLANDER	4	11,904	0.3360
178	TOYOTA	PRIUS	27	82,659	0.3266
179	TOYOTA	LEXUS ES	13	42,833	0.3035
180	JAGUAR LAND ROVER	LAND ROVER LR2	1	3,443	0.2904
181	BMW	Z4/M	1	3,637	0.2750
182	TOYOTA	VENZA	15	58,897	0.2547
183	HONDA	FIT	21	83,765	0.2507
184	SUBARU	OUTBACK	9	36,410	0.2472
185	HONDA	CR–V	40	171,943	0.2326
186	FORD MOTOR CO.	CROWN VICTORIA	8	36,101	0.2216
187	SAAB	9–3	1	4,593	0.2177
188	NISSAN	CUBE	6	28,243	0.2124
189	KIA	BORREGO	3	14714	0.2039
190	MERCEDES–BENZ	CLK–CLASS	3	15,654	0.1916
191	SUBARU	B9 TRIBECA	1	6,806	0.1469
192	BMW	MINI COOPER	6	51,935	0.1155
193	FORD MOTOR CO.	MERCURY MARINER	2	25,682	0.0779
194	ASTON MARTIN	DB9	0	741	0.0000

PRELIMINARY REPORT OF THEFT RATES FOR MODEL YEAR 2009 PASSENGER MOTOR VEHICLES STOLEN IN CALENDAR YEAR 2009—Continued

	Manufacturer	Make/model (line)	Thefts 2009	Production (Mfr's) 2009	2009 Theft rate (per 1,000 vehicles produced)
195	ASTON MARTIN	VANTAGE	0	582	0.0000
196	AUDI	AUDI S6	0	100	0.0000
197	BENTLEY MOTORS	ARNAGE	0	86	0.0000
198	BENTLEY MOTORS	AZURE	0	66	0.0000
199	BENTLEY MOTORS	BROOKLANDS	0	94	0.0000
200	BENTLEY MOTORS	CONTINENTAL	0	930	0.0000
201	CHRYSLER	DODGE VIPER	0	575	0.0000
202	FERRARI	141	0	109	0.0000
203	FERRARI	430	0	605	0.0000
204	FERRARI	612 SCAGLIETTI	0	29	0.0000
205	FERRARI	CALIFORNIA	0	53	0.0000
206	GENERAL MOTORS	CADILLAC FUNERAL COACH/HEARSE	0	714	0.0000
207	GENERAL MOTORS	CADILLAC LIMOUSINE	0	330	0.0000
208	GENERAL MOTORS	CADILLAC XLR	0	858	0.0000
209	GENERAL MOTORS	PONTIAC G3	0	6,237	0.0000
210	GENERAL MOTORS	SATURN ASTRA	0	851	0.0000
211	HYUNDAI	AZERA	0	5,062	0.0000
212	HYUNDAI	VERACRUZ	0	2,188	0.0000
213	JAGUAR LAND ROVER	VANDEN PLAS/SUPER V8	0	326	0.0000
214	JAGUAR LAND ROVER	XJ8/XJ8L	0	358	0.0000
215	JAGUAR LAND ROVER	XJR	0	11	0.0000
216	JAGUAR LAND ROVER	XK	0	903	0.0000
217	LAMBORGHINI	GALLARDO	0	281	0.0000
218	LAMBORGHINI	MURCIELAGO	0	110	0.0000
219	LOTUS	ELISE	0	120	0.0000
220	LOTUS	EXIGE	0	27	0.0000
221	MAZDA	MX–5 MIATA	0	4,293	0.0000
222	MERCEDES–BENZ	MAYBACH 57	0	27	0.0000
223	MERCEDES–BENZ	MAYBACH 62	0	18	0.0000
224	MERCEDES–BENZ	MAYBACH LANDAULET	0	2	0.0000
225	MERCEDES–BENZ	SLR–CLASS	0	69	0.0000
226	MITSUBISHI	ENDEAVOR	0	50	0.0000
227	NISSAN	INFINITI EX35	0	2,169	0.0000
228	ROLLS ROYCE	PHANTOM	0	409	0.0000
229	ROUSH PERFORMANCE	RPP MUSTANG	0	395	0.0000
230	SAAB	9–5	0	732	0.0000
231	SPYKER	C8	0	18	0.0000
232	SUZUKI	EQUATOR PICKUP	0	2,380	0.0000
233	SUZUKI	XL7	0	1,290	0.0000
234	TESLA	ROADSTER	0	900	0.0000
235	TOYOTA	LEXUS SC	0	511	0.0000
236	VOLVO	V50	0	1,913	0.0000
237	VOLVO	XC70	0	4,614	0.0000
238	VOLVO	XC90	0	6,806	0.000

Issued on: June 15, 2011.

Christopher J. Bonanti,

Associate Administrator for Rulemaking.

[FR Doc. 2011–15561 Filed 6–21–11; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[FWS–R7–ES–2011–N086; 70120–1113–0000–C4]

Endangered and Threatened Wildlife and Plants; Eskimo Curlew; Initiation of 5-Year Status Review

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Initiation of 5-year status review and request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the initiation of a 5-year status review for the Eskimo curlew (*Numenius borealis*), a bird species listed as endangered under the Endangered Species Act of 1973, as amended (Act). We conduct 5-year reviews to ensure that our classification of each species as threatened or endangered on the List of Endangered and Threatened Wildlife and Plants is accurate. We request any new information on this species that may have a bearing on its classification as endangered. Based on the results of this 5-year review, we will make a finding on whether this species is properly classified under the Act.

DATES: To allow us adequate time to conduct our 5-year review, we are

requesting that you submit your information no later than August 22, 2011. However, we accept new information about any listed species at any time.

ADDRESSES: Submit your comments and information on this species, as well as any request for information, by any one of the following methods. You may also view information and comments we receive in response to this notice, as well as other documentation in our files, at the following locations by appointment, during normal business hours.

E-mail: denise_walther@fws.gov; Use ''Eskimo curlew'' as the message subject line.

Fax: Attn: Denise Walther (907) 456–0208.

U.S. mail: Denise Walther, U.S. Fish and Wildlife Service, 101 12th Avenue, Room 110, Fairbanks, Alaska, 99701.

In-Person drop-off or Document review/pickup: You may drop off comments and information, review/obtain documents, or view received comments during regular business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Denise Walther, Endangered Species Biologist, at the address under **ADDRESSES** or by phone at (907) 456–0277.

SUPPLEMENTARY INFORMATION:

I. Background

We originally listed the Eskimo curlew (*Numenius borealis*) as endangered under the Endangered Species Preservation Act of 1966 on March 11, 1967 (32 FR 4001). No information on the biology of the species or the threats to it was presented in the listing. No critical habitat has been designated for the species. Eskimo curlews are thought to have once numbered in the hundreds of thousands (Gill *et al.* 1998). The population declined precipitously and approached extinction in the late 19th century. Spring market hunting in the midwestern United States during the late 1800s was clearly an important factor contributing to the species' decline. However, Gill *et al.* (1998) also implicate the conversion of prairie habitat to agriculture, fire suppression, and extinction of the Rocky Mountain grasshopper (*Melanoplus spretus*) in the rapid decline of Eskimo curlew. By 1900, sightings of Eskimo curlews were rare. The last confirmed observation took place in Nebraska in 1987.

Because Eskimo curlews were not well studied before their decline, we have very limited information on their biology. The following summary of their life history is based on Gollop *et al.* (1986), unless another citation is provided. The taxonomy, historical distribution, and ecology of Eskimo curlew is further summarized by Gill *et al.* (1998).

The only confirmed breeding grounds for the Eskimo curlew occurred in treeless tundra in the Northwest Territories, Canada, but their breeding range probably extended through similar habitats in northern Alaska and possibly eastern Siberia. Nests were simple depressions on bare ground with four eggs, one clutch per season. Hatching occurred during late June and early July. Primary foods on the breeding grounds were berries, particularly crowberries (*Empetrum nigrum*) and insects.

The Eskimo curlew migrated annually between breeding grounds in North America and wintering grounds in South America. In late summer and fall, the majority of birds migrated eastward across Alaska and Canada, where they continued to forage in heath-shrub habitats. Eskimo curlews staged in large numbers along the coast of Labrador, feeding on berries in nearby uplands and invertebrates in intertidal habitats (Gill *et al.* 1998), before continuing south 4000–5000 km (2500–3000 mi) over the Atlantic Ocean to South America. They then migrated south to wintering grounds in the Pampas of Argentina, southern Brazil, Uruguay, and Chile. There is some evidence that Eskimo curlews also overwintered in southern Patagonia, possibly leaving the Pampas in mid-winter (Gill *et al.* 1998). Spring migration probably began in late February to March and continued through May. The northward migration route through South America is unknown. However, Eskimo curlews are thought to have passed through Central America and crossed the Gulf of Mexico into Texas. They travelled northward through the midwestern United States, where they fed on grasshopper egg cases and emerging nymphs, other insects, and earthworms on burned and disturbed prairie and agricultural fields (Gill *et al.* 1998). Eskimo curlews then migrated northwestward through Canada, returning to the breeding grounds in late May.

II. Initiation of 5-Year Status Review

A. Why do we conduct a 5-year review?

Under the Act (16 U.S.C. 1531 *et seq.*), we maintain a List of Endangered and Threatened Wildlife and Plants (List) in the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for animals) and 17.12 (for plants). An informational copy of the List, which covers all listed species, is also available on our Internet site at *http://endangered.fws.gov/wildlife.html#Species.* Section 4(c)(2)(A) of the Act requires us to review the status of each listed species at least once every 5 years. Then, based on such review, under section 4(c)(2)(B), we determine whether any species should be removed from the List (delisted), reclassified from endangered to threatened, or reclassified from threatened to endangered. Any change in Federal classification requires a separate rulemaking process.

Our regulations in 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing the species we are reviewing. This notice announces our active 5-year status review of the endangered Eskimo curlew.

B. What information do we consider in our review?

We consider the best scientific and commercial data available at the time we conduct our review. This includes new information that has become available since our current listing determination or most recent status review of the species, such as new information regarding:

A. Any confirmed sightings;

B. Species biology, including but not limited to population trends, distribution, abundance, demographics, and genetics;

C. Habitat conditions, including but not limited to amount, distribution, and suitability;

D. Conservation measures that have been implemented that may benefit the species;

E. Threat status and trends (see five factors under heading ''How Do We Determine Whether a Species is Endangered or Threatened?''); and

F. Other new information, data, or corrections, including but not limited to taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

C. How do we determine whether a species is endangered or threatened?

Section 4(a)(1) of the Act requires that we determine whether a species is endangered or threatened based on one or more of the five following factors:

A. The present or threatened destruction, modification, or curtailment of its habitat or range;

B. Overutilization for commercial, recreational, scientific, or educational purposes;

C. Disease or predation;

D. The inadequacy of existing regulatory mechanisms; or

E. Other natural or manmade factors affecting its continued existence.

Under section 4(b)(1) of the Act, we are required to base our assessment of these factors solely on the best scientific and commercial data available.

D. What could happen as a result of our review?

For each species we review, if we find new information indicating a change in classification may be warranted, we may propose a new rule that could do one of the following:

A. Reclassify the species from threatened to endangered (uplist);

B. Reclassify the species from endangered to threatened (downlist); or

C. Remove the species from the List (delist).

If we determine that a change in classification is not warranted, then the species remains on the List under its current status.

We must support any delisting by the best scientific and commercial data available, and only consider delisting if such data substantiate that the species is neither endangered nor threatened for one or more of the following reasons:

A. The species is considered extinct;

B. The species is considered to be recovered; and/or

C. The original data available when the species was listed, or the interpretation of such data, were in error (50 CFR 424.11(d)).

E. Request for new information

To ensure that a 5-year review is complete and based on the best available scientific and commercial information, we request new information from the public, governmental agencies, Tribes, the scientific community, environmental entities, industry, and any other interested parties concerning the status of the species.

See ''What information do we consider in our review?'' for specific criteria. If you submit information, support it with documentation such as maps, bibliographic references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources.

F. Public Availability of Comments

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the offices where we receive comments.

III. Definitions

(A) *Species* includes any species or subspecies of fish, wildlife, or plant, and any distinct population segment of any species of vertebrate, which interbreeds when mature;

(B) *Endangered* means any species that is in danger of extinction throughout all or a significant portion of its range; and

(C) *Threatened* means any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.

IV. Authority

We publish this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: May 12, 2011.

LaVerne Smith,

Deputy Regional Director, Region 7, U.S. Fish and Wildlife Service.

[FR Doc. 2011–15355 Filed 6–21–11; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2010–0079; 92220–1113–0000–C3]

RIN 1018–AX27

Endangered and Threatened Wildlife and Plants; Proposed Rule To Establish a Manatee Refuge in Kings Bay, Citrus County, FL

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; availability of supplemental information.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose to establish a manatee refuge in Citrus County, Florida, in the waters of Kings Bay, including its tributaries and connected waters. We propose this action based on our determination that there is substantial evidence showing that certain waterborne activities would result in the taking of one or more manatees and that certain waterborne activities must be restricted to prevent the taking of one or more manatees in Kings Bay. We considered the biological needs of the manatee, the level of take at these sites, and the likelihood of additional take of manatees due to human activity at these sites in proposing this manatee refuge. These factors were the basis for establishing this area as a manatee refuge by a temporary emergency rule on November 9, 2010, which expired on March 15, 2011. We announced in the emergency rule that we would begin proceedings to establish this area as a manatee refuge. This proposed rule is part of that process. We also announce the availability of a draft environmental assessment for this action.

DATES: We will consider any comments on both the proposed rule and the draft environmental assessment that are received by the close of business on August 22, 2011 or at the public hearing. We will hold a public informational open house from 5:30 p.m. to 6:30 p.m., followed by a public hearing from 7 p.m. to 9 p.m., on July 7, 2011, at the location identified in the **ADDRESSES** section.

ADDRESSES: *Written comments:* You may submit comments on the proposed rule and draft environmental assessment (EA) by one of the following methods:

- *Electronically:* Go to the Federal eRulemanking Portal: *http://www.regulations.gov.* In the Enter Keyword or ID box, enter FWS–R4–ES–2010–0079, which is the docket number for this rulemaking. Then, in the Search panel at the top of the screen, under the Document Type heading, check the box next to Proposed Rules to locate this document. You may submit a comment by clicking on ''Submit Comments''
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: FWS–R4–ES–2010–0079; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, Suite MS 2042–PDM; Arlington, VA 22203.

We will not accept e-mail or faxes. We will post all information received on *http://www.regulations.gov.* This generally means that we will post any personal information you provide to us (see the Public Comments Solicited section below for more details).

Copies of Documents: The proposed rule and draft EA are available by the following methods. In addition, comments and materials we receive, as well as supporting documentation used in preparing this proposed rule will be available for public inspection:

(1) You can view them on *http://www.regulations.gov.* Go to the Federal eRulemaking Portal: *http://*

www.regulations.gov. In the Keyword box, enter Docket No. [FWS–R4–ES–2010–0079], which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document.

(2) You can make an appointment, during normal business hours, to view the documents, comments, and materials in person at the U.S. Fish and Wildlife Service, North Florida Ecological Services Office, 7915 Baymeadows Way, Suite 200, Jacksonville, Florida 32256; by telephone (904/731–3336); by facsimile (904/731–3045). If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

Public Hearing: We will hold a public hearing at the following location: College of Central Florida—Citrus Campus, CF Conference Center, 3800 S. Lecanto Hwy., Lecanto, FL 34461–9026 on July 7, 2011 (see Public Hearing section). Comments will be accepted orally or in writing at the public hearing.

FOR FURTHER INFORMATION CONTACT: Jim Valade, U.S. Fish and Wildlife Service, North Florida Ecological Services Office, 7915 Baymeadows Way, Suite 200, Jacksonville, Florida 32256; by telephone (904/731–3336); by facsimile (904/731–3045); by e-mail: *manatee@fws.gov;* or on-line at *http://www.fws.gov/northflorida.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Public Comments Solicited

To ensure that any final action resulting from this proposed rule will be as accurate and as effective as possible, we request that you send relevant information for our consideration. We request information from the public, government agencies, Native American Tribes, the scientific community, industry, and any other interested parties. Please make your comments as specific as possible and explain the basis for them. In addition, please include sufficient information with your comments to allow us to authenticate any scientific or commercial data you reference or provide. In particular, we seek comments concerning the following:

1. The reasons why this area should or should not be designated as a manatee refuge, including information that supports the need for any changes to the proposed manatee refuge;

2. Current or planned activities in the subject area and their possible effects on manatees;

3. Any foreseeable economic or other impacts resulting from the proposed designation;

4. Any substantive information on real or potential effects of the proposed manatee refuge on manatees; and

5. Any actions that could be considered in lieu of, or in conjunction with, the proposed designation that would provide equivalent protection to the manatee against the threat of take.

Prior to issuing a final rule on this proposed action and determining whether to prepare a finding of no significant impact or an Environmental Impact Statement, we will take into consideration comments and additional information we receive. Such information may lead to a final rule that differs from this proposal. All comments and recommendations, including names and addresses, will become part of the administrative record for the final rule.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a final decision, as the Endangered Species Act, the Marine Mammal Protection Act, and our implementing regulations direct that decisions be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your information concerning this proposal by one of the methods listed in the **ADDRESSES** section. We will not consider submissions sent by e-mail or fax or to an address not listed in the **ADDRESSES** section.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this personal identifying information from public review. However, we cannot guarantee that we will be able to do so. We will post hardcopy submissions on *http://www.regulations.gov.* Please note that comments submitted to this Web site are not immediately viewable. When you submit a comment, the system receives it immediately. However, the comment will not be publicly viewable until we post it, which might not occur until several days after submission.

Information and materials we receive, as well as supporting documentation we used in preparing this rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment during normal business hours, at the U.S. Fish and Wildlife Service, Jacksonville Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT** section).

Peer Review

In accordance with our policy on peer review, published on July 1, 1994 (59 FR 34270), we will provide copies of this proposed rule to three or more appropriate and independent specialists in order to solicit comments on the scientific data and assumptions underlying this proposed establishment of a manatee refuge. The purpose of such review is to ensure that the proposed rule is based on the best scientific information available. We will invite these peer reviewers to comment during the public comment period and will consider their comments and information on this proposed rule during preparation of a final determination.

We will consider all comments and information received from peer reviewers and other commenters during the 60-day comment period on this proposed rule in preparing a final rulemaking. Accordingly, the final decision may differ from this proposal.

Public Hearing

We have scheduled a formal public hearing to afford the general public and all interested parties with an opportunity to make formal oral comments on the proposed Federal manatee protection area.

We will hold the public hearing at the location listed in **ADDRESSES** on the date listed in **DATES**. The public hearing will last from 7 p.m. to 9 p.m. We will hold a public informational open house prior to the hearing from 5:30 p.m. to 6:30 p.m. to provide an additional opportunity for the public to gain information and ask questions about the proposed rule. This open house session should assist interested parties in preparing substantive comments on the proposed rule.

Persons needing reasonable accommodations in order to attend and participate in the public hearing should contact Chuck Underwood of the Jacksonville Field Office at 904–731–3332 or via e-mail to *manatee@fws.gov,* as soon as possible. In order to allow sufficient time to process requests, please contact us for assistance no later than one week before the hearing.

Written comments submitted during the comment period receive equal consideration with comments presented at a public hearing. All comments we receive at the public hearing, both verbal and written, will be considered in making our final decision.

Background

Previous Federal Actions

The West Indian manatee (*Trichechus manatus*) was listed as an endangered species on June 2, 1970 (35 FR 8491) under the Endangered Species Conservation Act of 1969 and this status was retained under the Endangered Species Act of 1973, as amended (ESA) (16 U.S.C. 1531 *et seq.*), and the population is further protected as a depleted stock under the Marine Mammal Protection Act of 1972, as amended (MMPA) (16 U.S.C. 1361 *et seq.*). On October 22, 1979, the U.S. Fish and Wildlife Service (Service) adopted a regulatory process to provide a means for establishing manatee protection areas in waters under the jurisdiction of the United States where manatees were taken by waterborne activities (44 FR 60964). The first manatee protection areas were designated in Kings Bay on November 12, 1980, for the purpose of preventing the take of manatees by harassment from waterborne activities and included the Banana Island Sanctuary, the Sunset Shores Sanctuary, and the Magnolia Springs Sanctuary (45 FR 74880). The Service subsequently designated four additional manatee protection areas in Kings Bay on June 13, 1994 and on October 16, 1998 (including the Buzzard Island Sanctuary, a sanctuary located along the north shore of Banana Island, the Warden Key Sanctuary, and the Three Sisters Springs Sanctuary, respectively) (59 FR 24654, and 63 FR 55553). To prevent the imminent take of manatees by waterborne activities, we published an emergency rule establishing the Kings Bay Manatee Refuge in Citrus County, Florida on November 9, 2010 (75 FR 68719). The Service now proposes to establish the Kings Bay Manatee Refuge throughout Kings Bay, while maintaining the 7 existing Manatee Sanctuaries in the bay.

The West Indian manatee includes two subspecies: The Florida manatee (*Trichechus manatus latirostris*) and the Antillean manatee (*Trichechus manatus manatus*). Florida manatees can be found throughout the southeastern United States, with Florida at the core of its range. Extensive efforts are ongoing by the Service and the Florida Fish and Wildlife Conservation Commission (Commission or FWC) to recover this species. In particular, significant efforts are made to minimize human-related threats and to attempt to prevent the number of manatees taken by human activities.

Take, as defined by section 3(19) of the ESA, means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, collect, or to attempt to engage in any such conduct. Harm is further defined by regulation at 50 CFR 17.3 to mean an act which actually kills or injures wildlife. Harass is also defined by regulation to mean any intentional or negligent act or omission which creates the likelihood of injury to wildlife by annoying it to such an extent as to significantly disrupt normal behavioral patterns, which include, but are not limited to, breeding, feeding, or sheltering (50 CFR 17.3). Take, as defined by section 3(13) of the MMPA, means to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal. Take is further defined in 50 CFR 18.3 to include, without limitation, any of the following: The collection of dead animals or parts thereof; the restraint or detention of a marine mammal, no matter how temporary; tagging a marine mammal; or the negligent or intentional operation of an aircraft or vessel, or the doing of any other negligent or intentional act which results in the disturbing or molesting of a marine mammal. Under section 3(18) of the MMPA, harassment is defined to include any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B). All takings, including takings by harassment, are prohibited.

The primary human-related causes of death and injury to manatees rangewide include watercraft-related strikes (impacts and/or propeller strikes), entrapment and/or crushing in water control structures (gates, locks, *etc.*), and entanglement in fishing lines, crab pot lines, *etc.* A 2005 analysis concluded that watercraft-related mortality was the leading cause of death for manatees throughout Florida (MPSWG 2005, p. 5). A subsequent threats analysis concluded that watercraft strikes and the potential loss of warm-water habitat pose the greatest threats to the Florida manatee population (Runge *et al.* 2007, p. 17).

The Service can prevent the taking of one or more manatees through the designation of manatee protection areas in the form of either a manatee refuge or a manatee sanctuary. Regulations authorizing designation of manatee refuges and sanctuaries in areas where restrictions or prohibitions on certain waterborne activities are needed to prevent the take of manatees are codified in 50 CFR 17 subpart J. A manatee refuge is defined as an area in which the Director has determined that: (1) Certain waterborne activities would take one or more manatees; or (2) certain waterborne activities must be restricted to prevent the take of one or more manatees, including but not limited to taking by harassment. A manatee sanctuary is an area where it has been determined that any waterborne activity would result in the taking of one or more manatees, including but not limited to a taking by harassment (50 CFR 17.102).

Kings Bay

The Florida manatee's range includes Kings Bay, Florida. Kings Bay is a large embayment located at the headwaters of the Crystal River, a tidal river, located on Florida's west coast. Springs are the primary water source for this estuarine system; a recent report describes 70 springs that discharge warm artesian water into Kings Bay (Vanasse, Hangen, and Brustlin, Inc., 2010, p. 1). Kings Bay is located within the City of Crystal River's city limits, in Citrus County, Florida. Citrus County and the City of Crystal River are an integral part of ''Florida's Nature Coast'', a northwest Florida region marketed for outdoor recreational opportunities, including opportunities for viewing manatees (Nature Coast Coalition 2010 Web site). In addition to viewing manatees, area recreationists engage in snorkeling and diving, boating, canoeing and kayaking, fishing, waterskiing, and other activities (Gold 2008, pps. 4–5). Local eco-tour operators, dive shops, marinas, hotels and motels, restaurants, and other businesses benefit from these activities (Buckingham 1990, p. 6).

The Kings Bay springs constitute one of the most important natural warm-water refuges for manatees. Manatees have historically been attracted to the warm, spring-fed waters in Kings Bay where they retreat from the cold during the winter. More recently, manatees have begun to use this area during the warm summer months as well. Wintering manatees have been the focus of a manatee viewing industry for many years, and bay waters are widely used by commercial and recreational waterway users for a variety of activities throughout the year. Manatees are struck and killed or injured by boats operating in Kings Bay. Manatees are

harassed by the viewing public. The number of manatees struck and killed by boats in Kings Bay is increasing, as are the number of public reports of acts of manatee harassment.

Waterborne activities that occur on the Service's Crystal River National Wildlife Refuge (NWR) property in Kings Bay that are known to take manatees are prohibited pursuant to 50 CFR 17 subpart J and the National Wildlife Refuge Improvement Act (16 U.S.C. 668dd–668ee), which allows the Service to issue special-use permits (SUPs) for commercial and retail activities that occur on NWR property. National Wildlife Refuges are Service-owned or managed lands that are managed to broadly conserve, manage, and restore fish, wildlife, and plant resources and their habitats. The Banana Island Manatee Sanctuary, designated under 50 CFR 17 subpart J, prohibits all waterborne activities from occurring on some submerged lands owned by this NWR. Commercial and retail activities that occur on NWR-owned land include manatee viewing, diving, snorkeling, videography, and others. Businesses wanting to engage in these activities on NWR property must obtain SUPs from Crystal River NWR. These permits are conditioned to require permittees to take those steps needed to make sure that their activities and those of their customers do not harass or otherwise take manatees.

Watercraft associated with recreational and commercial activities strike and kill manatees. In the State's northwest region, where Kings Bay is located, adult manatee mortality is almost equally split between human-related and natural causes, with watercraft collisions being the leading source of human-caused mortality. From 1974 through 2010, collisions with watercraft killed 16 manatees in Kings Bay. Eleven of these deaths occurred between 2003 and 2010, including seven that occurred during the summer.

Manatee viewing activities provide a significant source of revenue to the local economy (Buckingham 1990, p. 6). Local eco-tour businesses bring visitors out to Kings Bay where visitors view manatees while in the water, from boats, and from other vantage points. Some manatees initiate encounters with visitors, but most manatees avoid or ignore encounters with people, preferring to frequent manatee sanctuaries where all human activities are prohibited. Some manatees are harassed by visitors, despite the fact that all forms of harassment are prohibited by law.

Hartman (1979, pp. 128–131) was the first to observe and describe how manatees respond to the presence of people in the water, observing that most manatees tended to avoid people, some ignored people, a few approached people with curiosity and then left, and some approached and solicited interactions with people. These observations were made in Kings Bay's warm water springs and the author correlated a reduction in the number of manatees using the Main Spring with an increasing number of people (Hartman 1979, p. 131). Concern has been expressed about manatees displaced from warm water springs for prolonged periods of time; prolonged exposure to cold can be fatal to manatees, especially for smaller animals (O'Shea 1995, p. 304). Hartman (1979, p. 126) believed that manatees in Kings Bay are harassed by people in the water and by boats.

Researchers have observed and documented manatee responses to people and boats (Sorice *et al.* 2003, p. 324). Researchers noted increases in swimming, milling, and cavorting behaviors and decreases in resting, feeding, and nursing behaviors in the presence of increasing numbers of people and boats (Abernathy 1995, pp. 23–26; Wooding 1997, p. 1; King and Heinen 2004, pp. 230–231). They also observed that increases in numbers of boats and people prompted manatees to use other areas (Kochman *et al.* 1985, pp. 922–924; Buckingham *et al.* 1999, p. 514). However, none of these studies' observations of manatee responses to viewing participants and boats suggest that harm (killing or injuring of manatees) has occurred or is occurring (Sorice *et al.* 2003, p. 320). Nor have there been any significant increases in the number of cold-related injuries and mortalities in the northwest Florida region. Manatee survival rates in the northwest region are among the highest in Florida (FWC FWRI Manatee Mortality Database 2010 Web site; Runge *et al.* 2007, p. 20).

Observations of manatee harassment in Kings Bay prompted the Service to promulgate a rule in 1979 that allowed the agency to designate manatee protection areas where certain waterborne activities, including boating and swimming, could be prohibited in order to ''reduce the incidence of manatee injuries and deaths'' and to ''lessen the likelihood that manatees will encounter boats and people'' (44 FR 60964). Subsequently, three manatee sanctuaries were designated in Kings Bay in 1980 (45 FR 74880; November 12, 1980) and, in 1983, the Service purchased lands in and around Kings Bay and established the Crystal River NWR for the purpose of protecting manatees and to educate the public about manatees.

In 1994, citing a doubling of the number of manatees in the area since 1980, a large increase in the number of visitors, the inability of the existing sanctuaries to provide sufficient shelter for manatees, and reports of increasing manatee harassment, the Service designated three additional sanctuaries in Kings Bay to prevent the take of manatees by harassment (59 FR 24654; May 12, 1994). This expansion was followed by the addition of another sanctuary in 1998, similarly justified by reports of increasing harassment and observations of increasing numbers of manatees, increasing numbers of recreational divers and snorkelers, and insufficient space for manatees to rest, free from harassment (63 FR 55553; October 16, 1998: See table 1.).

TABLE 1—INFORMATION JUSTIFYING PREVIOUS MANATEE SANCTUARY DESIGNATIONS IN KINGS BAY, FLORIDA.

Date of Kings Bay manatee sanctuary designations	Approximate number of manatees using Kings Bay	Estimated number of people viewing manatees	Number of sanctuary designations NEW (TOTAL)
November 12, 1980 (45 FR 74880)	100	30,000 to 40,000	3(3)
May 12, 1994 (59 FR 24654)	240	60,000 to 80,000	3(6)
October 16, 1998 (63 FR 55553)	250	100,000	1(7)

Over the last 30 years (1980–2010), the Service and the State of Florida have created a network of manatee protection areas within the Kings Bay area. This network was designed to prevent the take of manatees by waterborne

activities, including but not limited to, boating and manatee viewing activities, and was established to allow manatees to continue to gain access to critical warm-water areas and important resting and foraging areas. During the manatee season, the network includes seven Federal manatee sanctuaries (which are described in our regulations at 50 CFR 17.108(a)(1)–(a)(7)) and five State manatee protection zones (as described in Chapter 68C–22, ''The Florida Manatee Sanctuary Act'' (2010)).

The seven Federal sanctuaries are located at heavily-used winter, warm-water sites (springs) and foraging areas and preclude all waterborne activities within their boundaries, preventing take from both boating and manatee viewing within these areas. The State protection zones include year-round idle and slow speed zones that prevent the take of manatees from high speed watercraft collisions. Given the State's statutory responsibilities for balancing the needs of manatees with the needs of the boating community, the State designated a 35 MPH (daytime)/25 MPH (nighttime) watersports area in Kings Bay. This area encircles Buzzard Island in the center of the bay.

This network of manatee protection areas is enforced by Service, State, and local law enforcement officers. Extensive outreach and education programs support the protection area network, encouraging the public who engage in waterborne activities, including boating, manatee viewing activities, and others, to avoid taking manatees.

Current

Similar to previous circumstances that warranted increases in the level of protection for manatees in Kings Bay, the number of manatees using Kings Bay more than doubled since 1998 (from 250 animals to 566 animals) (Kleen 2010, pers. com.); the number of residents, visitors, and boats increased; and the amount of space in the existing sanctuaries became insufficient to provide this number of manatees with shelter free from harassment. In addition, the number of manatees struck and killed by boats in Kings Bay has increased since 2002, when the watersports area was created.

The manatee population in northwest Florida grew at a rate of 4.0 percent per year through 2000, based on an assessment of adult survival rates (Runge *et al.* 2004, p. 371). Consistent with this rate of increase, the number of manatees counted in the region has increased, as well. Aerial counts were first conducted during the winter of 1983–1984, when 142 manatees were sighted in Citrus County; 124 of these animals were sighted in Kings Bay and Crystal River. In January 2010, Crystal River NWR researchers counted 646 manatees in Citrus County's coastal waters, including 566 manatees in Kings Bay. This is the highest number of manatees ever counted in this region and in Kings Bay (Kleen 2010, pers. com.). Aerial observations of manatees in Kings Bay during especially cold periods include sightings of manatees within the sanctuary areas and in lesser springs. In recent years, dozens of manatees are seen sheltering just outside of the sanctuary boundaries because the sanctuaries are overcrowded. Some animals shelter in some of Kings Bay's smaller, unprotected springs, including House Spring, Jurassic Spring, and an unnamed spring just east of the mouth of Three Sisters Springs run. As many as 20 animals have been seen in each of these sites on particularly cold days (Kleen 2010, pers. com.).

The number of Citrus County residents increased by 19.8 percent (an average annual growth rate of 2.5 percent per year), from 118,085 to 141,416, between 2000 and 2008 (U.S. Census Bureau 2010 Web site). Concurrent with this increase in number of residents, the number of boats registered in Citrus County increased by 36.2 percent at an average annual growth rate of 4.0 percent per year. In 2009, there were 17,601 boats registered in Citrus County, 4,675 more than the 12,926 vessels registered there in 2000 (FDHSMV 2010 Web site). While the number of visitor-owned watercraft that use Citrus County waterways, including Kings Bay, is unknown, this number is likely increasing, based on county revenue trends that describe an increasing number of visitors to the area. Revenue trends associated with businesses that cater to visitors, including Citrus County lodging and food service revenues and tourist tax revenues, have increased by 178 percent and 214 percent, respectively, over the past 10 years, suggesting an increase in the number of visitors to the area (U.S. Census Bureau 2010 Web site). Tourism surveys suggest that about half of all visitors to the area come to Citrus County to enjoy water-based activities that include manatee viewing, snorkeling, and diving (Gold 2008, pgs. 4–5).

From 1974 through 2010, collisions with watercraft killed 60 manatees in Citrus County waterways, including 16 manatees in Kings Bay. Thirteen of the 16 Kings Bay watercraft-related deaths occurred within the past 10 years. In 2008, FWC recorded the highest number (8) of manatees ever killed by watercraft in Citrus County and three of these carcasses were recovered in Kings Bay (FWC FWRI Manatee Mortality Database 2010 Web site).

While watercraft-related deaths occur throughout the year in Citrus County, 7 of the 16 watercraft-related deaths that occurred in Kings Bay took place during those times of the year when the watersports area designated by the State of Florida in 2002 is in effect (May 1 to August 30). Three of these carcasses were recovered within the watersports area. Two deaths are known to have occurred after 2002 within the watersports area. In May 2004, observers witnessed a boat striking a manatee in the watersports area; a carcass was recovered nearby the following day. In July 2007, a severely-injured manatee was observed in the watersports area; the animal died before it could be rescued. Its carcass was recovered on-site and it was determined to have died from acute propeller lacerations (FWC FWRI Manatee Mortality Database 2010 Web site).

Every year, manatees are entangled in fishing lines, float lines, mooring lines, and other types of gear. In extreme cases, entangled manatees can die when entangling gear cuts into their hide, causing sepsis and the occasional loss of limbs. Many entangled animals are rescued. In cases when animals are superficially entangled, entangling gear is removed and the animals are released on-site. In more severe cases, manatees are transported to rehabilitation facilities where they are treated for injuries and infections associated with entanglements. There are 30 known cases of manatee entanglements from Citrus County, including 10 from Kings Bay. Fourteen of these cases include manatees entangled in crab pot float lines, including four from Kings Bay. The remaining cases from Kings Bay include four from fishing lines and two from mooring lines. County-wide records of entanglements include 24 rescues and 4 deaths. More than half of these are known to have occurred during the past 15 years (U.S. Fish and Wildlife Service Manatee Rescue Rehabilitation and Release Program entanglements unpubl. data).

Manatee harassment, largely associated with wintertime manatee viewing activities, occurs in Kings Bay, and a variety of methods are being used to help prevent and minimize harassment from occurring. The Service, State, nongovernment organizations, and private companies prepare and distribute outreach materials to manatee-viewing recreationists to familiarize them with best practices to

follow when in the water with manatees. Best practices include the ''Manatee Viewing Guidelines,'' developed by the Service and partners. Outreach materials include, among other things, handouts, kiosks, signs, and videos. The Crystal River NWR developed ''Manatee Manners,'' a video that dive shops and kayak outfitters are required to show their customers before they enter Kings Bay. These businesses take visitors to see manatees in Kings Bay, including on refuge-owned land. As commercial interests conducting business on Crystal River Refuge-owned land, they are required to obtain SUPs, which are conditioned to insure that the permittees and their designees do not take manatees. Crystal River NWR also maintains a visitor center where guests are provided with outreach materials. The Crystal River Refuge's ''Manatee Watch'' volunteer network places volunteers in kayaks near the sanctuaries to educate visitors and report infractions when they occur.

Federal regulations include 50 CFR 17.100—108, which provide for enforcement of manatee protection measures, and State regulations include provisions of the State's Florida Manatee Sanctuary Act as codified in 68 C—22 of the Florida Administrative Code. State and Federal officers have been cross-deputized and can enforce both State and Federal regulations. The Service, State, and other law enforcement agencies actively enforce harassment regulations in Citrus County and in Kings Bay. Cited acts of harassment include trespass by manatee-viewing individuals into manatee sanctuaries where the Service has determined that any waterborne activity occurring within these areas would result in take of manatees, including but not limited to take by harassment. Indirectly, the presence of large numbers of people in the vicinity of manatees may cause some animals to abandon the area, another form of harassment. Outside of these areas, the public disturbs and occasionally harasses manatees while engaged in viewing and other waterborne activities. When observed, violators are warned or cited. State violations include boaters traveling at speeds in excess of those described by law within specific areas.

Given variations in enforcement practices and recordkeeping systems, these records are not used to describe trends in harassment activity.

Summary

Based on current and historical data that document increasing numbers of manatees, waterway users, watercraft-related manatee deaths and injuries, and reports of manatee harassment in Kings Bay, we conclude that the take of manatees is occurring and increasing in this area. Sources of information include U.S. Geological Survey, the FWC, manatee experts, the public, and peer-reviewed literature. Future take would occur without additional protection measures; and we do not anticipate any alternative protection measures being enacted by other agencies in sufficient time to reduce the likelihood of take. For these reasons, we believe the establishment of an additional manatee protection area is needed to prevent the take of manatees. The proposed manatee refuge covers the same geographical area as defined by the November 9, 2010, emergency rule (75 FR 68719).

Proposal

To prevent the take of manatees, the Service and the State of Florida have designated a network of manatee protection areas at sites throughout Florida where threats to manatees have been well-documented and where manatees are known to frequently occur. This network supports our goal of providing areas of protected habitat throughout peninsular Florida, adequate to satisfy the biological needs of the species. We propose to enhance this network by establishing an additional manatee protection area, *i.e.,* a manatee refuge, in Kings Bay, a waterbody located in Crystal River, Citrus County, Florida.

Under the proposed manatee refuge designation, refuge restrictions would improve the Service's ability to address takings associated with watercraft and with manatee viewing activities. Restrictions would require all watercraft to operate at slow speed throughout Kings Bay, except in those areas where more restrictive measures are in place (idle speed zones, no entry areas, and sanctuaries), to reduce the number of watercraft-related deaths and injuries occurring in Kings Bay. Harassment associated with manatee viewing can be controlled through the establishment of no-entry areas not to exceed specified distances around existing manatee sanctuaries, the designation of no-entry areas at lesser springs when needed, and the identification of manatee refuge-specific prohibitions.

Proposed Kings Bay Manatee Refuge

Location

The Service proposes to designate the waters of Kings Bay as a manatee refuge. These waters include that tract of submerged land that includes all waters of Kings Bay, including all tributaries and adjoining waterbodies, upstream of the confluence of Kings Bay and Crystal River, described by a line that bears North 53°00′00″ East (True) from the northeasternmost point of an island on the southwesterly shore of Crystal River (approximate latitude 28°53′32″ North, approximate longitude 82°36′23″ West) to the southwesternmost point of a peninsula of Magnolia Shores (approximate latitude 28°53′38″ North, approximate longitude 82°36′16″ West). See Map ''Kings Bay Manatee Refuge''

The proposed manatee refuge encompasses seven existing Federal manatee sanctuaries, described in 50 CFR 17.108: the Banana Island Sanctuary (aka the King Spring Sanctuary), the Sunset Shores Sanctuary, the Magnolia Springs Sanctuary (including Gator Hole), the Buzzard Island Sanctuary, a sanctuary located along the north shore of Banana Island, the Warden Key Sanctuary, and the Three Sisters Springs Sanctuary. The existing sanctuaries are in effect from November 15 to March 31 (the manatee season). The proposed manatee refuge measures would be in effect in Kings Bay as described below.

Manatee Refuge Measures

The proposed manatee refuge measures, described in more detail below, include:

- Maintaining the 7 existing manatee sanctuaries where all waterborne activities are prohibited November 15–March 31;
- Restricting boat speeds throughout the refuge at all times;
- 13 specifically prohibited activities throughout the manatee refuge at all times;
- Requiring manatee-safe fishing lines, float lines, and mooring lines at all times;
- Temporary 'no-entry' areas adjacent to existing sanctuaries and several additional springs during the manatee season (November 15–March 31;
- Temporary 'no-entry' areas prior to or after the manatee season during unusual cold events; and,
- Limited exceptions for adjoining property owners and their designees.

Existing Manatee Sanctuaries

All 7 currently existing manatee sanctuaries in Kings Bay, where all waterborne activities are prohibited November 15–March 31, will remain in effect.

Boat Speeds

To prevent the take of one or more manatees killed and injured by high-speed watercraft, we propose to restrict boat speeds in Kings Bay to slow speed

throughout the year except in those areas where more restrictive measures are in place. Within the Kings Bay Manatee Refuge, all watercraft would be required to operate at slow speeds throughout Kings Bay, except in those areas with more restrictive measures such as idle speed zones, no-entry areas, and sanctuaries. Slow speed is defined as the speed at which a boat is fully off plane and completely settled in the water. By slowing all boats down within this area, collisions with manatees in Kings Bay can be prevented.

Manatee Viewing and Other Waterborne Activities

To prevent the take of one or more manatees associated with manatee viewing and other waterborne activities, we specify prohibitions that would be in effect throughout the year. Pursuant to the ESA and MMPA, all takings, including takings by harassment, are prohibited throughout the year, wherever they may occur. In regard to these prohibited activities, we consider a resting manatee to be a mostly motionless manatee on the water bottom, in the water column, or on the water's surface that rises to the surface to breathe. While resting, a manatee may make minor changes in its posture and may slightly shift its position. Minor changes in posture occur when manatees breathe or roll. Resting manatees may also make slight movements with their flippers or tail to compensate for draft, *etc.* (Hartman 1979, pp. 82–84). To prevent the take of manatees by individuals engaged in waterborne activities while in the water, in boats, or on-shore within the Kings Bay Manatee Refuge, we specifically identify and prohibit the following activities:

(i) Chasing or pursuing a manatee(s).

(ii) Disturbing or touching a resting or feeding manatee(s).

(iii) Diving from the surface onto resting or feeding manatee(s).

(iv) Cornering or surrounding or attempting to corner or surround a manatee(s).

(v) Riding, holding, grabbing, or pinching or attempting to ride, hold, grab, or pinch a manatee(s).

(vi) Poking, prodding, or stabbing or attempting to poke, prod, or stab a manatee(s) with anything, including your hands and feet.

(vii) Standing on or attempting to stand on a manatee(s).

(viii) Separating a mother and calf or attempting to separate a mother and calf.

(ix) Separating a manatee(s) from a group or attempting to separate a manatee(s) from a group.

(x) Giving a manatee(s) anything to eat or drink or attempting to give a manatee(s) anything to eat or drink.

(xi) Actively initiating contact with a belted and/or tagged manatee(s) and associated gear, including any belts, harnesses, tracking devices, or antennae.

(xii) Interfering with rescue and research activities.

(xiii) Using mooring and float lines that can entangle manatees.

In addition, the following waterborne activities are prohibited within Three Sisters Springs from November 15 through March 31:

a. Entering Three Sisters Springs between 6 p.m. and 7 a.m.

b. Scuba diving.

c. Fishing, including but not limited to fishing by hook and line, by cast net, and by spear.

Fishing Lines, Float Lines, Mooring Lines, and Other Types of Gear in Kings Bay

To prevent one or more manatees from becoming entangled in fishing lines, float lines, mooring lines, and other types of gear in Kings Bay, we propose to require the use of manatee-safe lines and other measures to prevent take from occurring throughout the year. Within Kings Bay, users of float lines, mooring lines, and other types of entangling gear would be required to use manatee-safe lines and practices that would prevent one or more manatees from being entangled, injured, or killed in this type of gear (refer to the list of prohibited activities above). Manatee-safe lines are lines that do not entangle manatees. Manatee-safe lines include stiffened lines and lines that, when in use, are kept taut and unable to entangle manatees. Examples include, but are not limited to, lines that incorporate stiffeners such as wire, lines enclosed in hose or PVC, and others. Lines should not be discarded in Kings Bay where they can continue to pose a threat to manatees. Monofilament recycling programs and the State of Florida's derelict crab pot removal program provide additional means for reducing the number of lines discarded in this area.

Temporary No-Entry Areas (November 15 Through March 31)

To insure sufficient space within the Kings Bay Manatee Refuge for manatees to shelter, rest, and feed, free from harassment both in the vicinity of the existing sanctuaries and at House Spring, Jurassic Spring, and Idiot's Delight Number 2 Spring, we propose to create temporary no-entry areas during the manatee season (between November 15 and March 31). Pursuant to Subpart J, all waterborne activities would continue to be prohibited within existing Federal manatee sanctuaries. Because there is insufficient space in the existing sanctuaries for all manatees that use Kings Bay to shelter, rest, and feed, free from harassment, we propose to create temporary no-entry areas outside of and adjacent to the existing sanctuaries to insure adequate room for manatees wanting to access these sites when space is needed. We also propose to create no-entry areas around House Spring, Jurassic Spring, and Idiot's Delight Number 2 Spring when these springs are occupied by manatees in need of shelter free from harassment. By providing manatees with additional space in areas where all waterborne activities are prohibited, we can prevent take of manatees in these areas from manatee viewing and other waterborne activities.

Temporary No-Entry Areas (April 1 Through November 14)

To prevent the take of manatees sheltering in Kings Bay from cold weather that occurs outside of the manatee season (November 15 to March 31), temporary no-entry areas may be proposed and put in effect during early onset and protracted cold weather events that occur outside of the manatee season. Manatees that appear in Kings Bay during cold fronts that pre-date the start of the manatee season are especially vulnerable to harassment because none of the sanctuaries and no entry areas are in effect prior to November 15. Similarly, none of these measures are in effect after March 31, during those times when cold weather continues beyond this period of time. In April 2010, the Service asked the public to voluntarily stay out of existing manatee sanctuaries after the close of the manatee season due to protracted cold weather and the continued presence of manatees at these sites. While the public generally complied with the request, some people did not and manatees were harassed.

By designating temporary no-entry areas prior to November 15 and after March 31 during cold fronts when manatees are present, manatee harassment that could occur during these times can be prevented. Designations would remain in effect for the duration of a cold front and only when manatees are present; manatee presence at warm-water sites during unseasonal cold events typically lasts for several days or less. Temporary designations would remain in effect for no longer than 14 days.

Exceptions for Adjoining Property Owners and Their Designees

Property owners and their designees (including but not limited to guests and contractors) who own property that adjoins designated no-entry areas would continue to be able to access their property by obtaining an exception from the Crystal River NWR that would allow them to operate boats within the adjoining no-entry area for purposes of access and property maintenance. The Crystal River NWR would continue to provide adjoining property owners and their designees with a sticker or letter of authorization that identifies their boats as authorized to access no-entry areas. Boats owned by excepted owners would be required to be marked by stickers and would be required to operate within designated areas at idle speed. Designees with a letter of authorization would be required to have a copy of the letter in their possession while operating within a designated area and would be required to operate at idle speed.

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, *etc.*

Required Determinations

Regulatory Planning and Review

In accordance with the criteria in Executive Order 12866, this proposed rule is not a significant regulatory action. The Office of Management and Budget makes the final determination under Executive Order 12866.

a. This proposed rule would not have an annual economic impact of over $100 million or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. A cost-benefit analysis is not required. It is not expected that significant economic impact would result from the establishment of a manatee refuge (approximately 530 acres) in Citrus County in the State of Florida.

b. This proposed rule, if implemented, would not create inconsistencies with other agency actions. The proposed rule is consistent with and complimentary to other existing agency actions. Existing agency actions currently in effect in Kings Bay include manatee protection areas. The proposed rule is based on the authorities used to create these areas and enhances the ability of these locally accepted designations to protect manatees from harassment and watercraft collisions.

c. This proposed rule would not materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients. Minimal restrictions to existing human uses of the proposed site would result from this proposed rule, but the restrictions are believed to enhance manatee viewing opportunities. No entitlements, grants, user fees, loan programs, or rights and obligations of their recipients are expected to occur.

d. This proposed rule would not raise novel legal or policy issues. We have previously established other manatee protection areas.

The purpose of this proposed rule is to establish a manatee protection area in Citrus County, Florida. The area includes the waters of Kings Bay and connecting waters and tributaries, upstream of the confluence of the Crystal River and Kings Bay. We are proposing to prevent the taking of one or more manatees by managing human activities in this area. The refuge would incorporate an existing network of Federal manatee sanctuaries. Affected waterborne activities would include swimming, diving (including skin and scuba diving), snorkeling, water skiing, surfing (including wind surfing), fishing, and the use of watercraft and other vessels. This rule could result in impacts to manatee viewing activities, recreational boaters, commercial charter boats, and commercial fishermen, primarily in the form of additional restrictions on manatee viewing activities and boat speed restrictions in specific areas. The Service could experience increased administrative costs due to this proposed rule. In addition, the rule would be expected to produce economic benefits for some parties as a result of increased manatee protection and decreased boat speeds within the area of the manatee refuge.

Regulatory impact analyses require the comparison of expected costs and benefits of the proposed rule against a baseline, which typically reflects the regulatory requirements in existence prior to the rulemaking. For purposes of this analysis, the baseline assumes that the Service takes no additional regulatory actions to protect the manatee. In fact, even with no further activity by the Service, an extensive system of manatee protection areas is already in place within the area of the proposed manatee refuge. As discussed below, in the regulatory impact analysis where we compare expected costs and benefits of the proposed changes, the economic impact of establishing this manatee refuge is not expected to be significant.

The economic impacts of this proposed rule are due to changes within the proposed manatee refuge area. Proposed restrictions associated with a newly designated manatee refuge would require all watercraft to operate at slow or idle speeds outside of the no-entry areas, as posted, to further minimize the number of watercraft-related manatee deaths and injuries occurring in Kings Bay. Harassment associated with manatee viewing activities would be controlled through the ability to designate temporary no-entry areas, enforce regulatory prohibitions, and an education program that addresses all individuals engaged in manatee viewing activities throughout the bay.

In order to gauge the economic effect of this proposed rule, both benefits and costs must be considered. Potential economic benefits related to this proposed rule include: Increased manatee protection and tourism related to manatee viewing, increased property values, increased boater safety, increased swimmer safety, improved fisheries health, and decreased shoreline maintenance costs. Potential economic costs are related to increased administrative activities related to implementing the rule and restrictions on certain waterborne activities. Economic costs would be measured primarily by the number of recreationists who use alternative sites for their activity or have a reduced quality of the waterborne activity experience in the designated manatee refuge. In addition, there may be some impact on commercial fishing because of the need to maintain slower speeds. While the State of Florida has over 7.5 million acres of waterways, this proposed rule would affect only 530 acres of the State's waterways and these 530 acres are currently regulated to

protect manatees. The proposed rule increases this protection by: Allowing for a limited expansion of existing sanctuary boundaries; establishing the ability to temporarily designate three discrete no entry areas; creating a discrete, 4-month-long, restricted slow-speed area within existing slow and idle speed areas; and by specifically prohibiting actions known to harass manatees. As detailed below, designation of this manatee refuge as proposed in this rule is not expected to affect enough waterborne activity to create a significant economic impact (that is, the rule would not have an annual impact of over $100 million).

Economic Benefits

We believe that the proposed establishment of Kings Bay Manatee Refuge would increase the level of manatee protection in these areas. Improved protection for the manatee may result in direct economic benefits by insuring the continued, local presence of viewable manatees and insuring the continued existence of the manatee viewing industry. Indirect benefits include the protection of private and publicly owned shorelines from high-speed wakes, the protection of aquatic vegetation from losses due to excessive turbidity caused by high-speed boat traffic, increased property values, and reductions in high-speed boating-related human deaths and injuries.

The public's support for manatees and their protection has been examined through contingent value studies (Bendle and Bell 1995, pp. 8–17; Fishkind and Associates 1993, pp. 5–11). These economic studies characterized the value placed by the public on this resource and determined that the public's willingness to pay for manatee protection is significant and that public support for manatee protection regulations in general, such as that described in the proposed rule, exists.

Bendle and Bell (1995, p. ii) conducted a representative survey of Florida residents in general (through random sample) and attempted to answer the question, ''How much are Florida residents willing to pay to cover the costs associated with protecting the manatee?'' In 1993 dollars, efforts to protect the manatee population as a whole were valued at an estimated $2.6 billion or $14.78 per household (or $4.03 billion or $22.91 per household, when adjusted to reflect 2011 monetary values). Based on surveys of north Florida residents, Fishkind and Associates (1993, p. 11) estimated that adult Florida residents would be willing to pay $30 per year in 1992 dollars (or $47.70 per year when adjusted to reflect 2011 monetary values) to help compensate for the adverse economic effects, if any, of protecting the manatee population (Fishkind and Associates 1993, pp. 28–30).

It is difficult to apply the results of these studies to the proposed rule, because neither study measures an impact similar to that associated with this rulemaking, which applies only to the Kings Bay area. For example, the Fishkind and Associates study (1993, p. 1) was designed to gauge the economic impact of the Florida Manatee Sanctuary Act. First, the estimates of economic benefit were predicated on a different baseline in terms of both the manatee population being protected at that time versus now, and the regulatory conditions, such as manatee protection areas, that were in existence at the time. Second, this study is not clear about the type and extent of manatee protection; it does not clearly state if protection refers solely to the designation of manatee protection areas or if protection is interpreted to include implementation and enforcement of protection measures. The study also does not clearly state whether residents are willing to pay for manatee protection within a specific region or for manatee protection throughout the State of Florida. While neither of these studies is specific enough to apply to this proposed rule, they do provide an indication that the public confers substantial value on the protection of manatees.

Another potential economic benefit is continued and increased tourism that likely results from an increase in manatee protection. Citrus County and Kings Bay are nationally and internationally recognized as primary destinations for winter-time manatee viewing. Surveys of visitors to Citrus County estimate that about half come to enjoy water-based activities, including manatee viewing, snorkeling, and diving (in order of preference) (Gold 2008, pp. 4–8). Hundreds of thousands of individuals are believed to engage in these activities each winter, and the number of participants is thought to be increasing.

Visitors and local residents view manatees in Kings Bay from boats or in the water on their own or through local eco-tour operators. Visitors may pay eco-tour operators to equip them and take them out onto Kings Bay to view manatees; vendors provide both in-water and on-water experiences. In-water rentals include wetsuits, masks, snorkels, and related gear. On-water rentals include canoe, kayak, and other boat-type rentals. Other visitors travel to the area and engage in manatee viewing activities using their own equipment, including boats and other needed gear. Many visitors stay at local hotels and eat at local restaurants. There are no reports or estimates of direct costs and expenditures associated with manatee viewing.

While there is no information on the number of boats associated with manatee viewing, including boats used by residents, boats trailered to the area by visitors, boats used to transport eco-tour clients, or boats leased to individuals watching manatees, a recent evaluation on the impact of boating on Florida, Florida's North Central Region, and Citrus County suggests that the overall economic impact of manatee viewing is important (FWC 2009 Online Boating Economic Impact Model Web site).

FWC's 2006 evaluation of Citrus County boating activities documented 14,304 county-registered boats (13,283 power boats and 1,021 non-power boats, including 903 kayaks and canoes) and 402,029 boat days in Citrus County waters. Over 60 percent of the boat trips taken by these boats occurred in Citrus County. Local boat ramp infrastructure emphasizes salt water destinations (calculated 2006 ramp lane capacities provide access for 10,620 launches, including 8,883 saltwater launches and 1,737 freshwater launches). The economic significance of Citrus County's registered boats and their activities is estimated at $104,740,000 annually in 2006 dollars (or $116,261,400 when adjusted to reflect 2011 monetary values); $63,513,400 (or $70,449,874 in 2011 monetary values) of this amount is spent on boat trips, including $8,549,200 (or $9,489,612 in 2011 monetary values) on lodging (14 percent) and $9,060,500 (or $10,057,155 in 2011 monetary values) on food. The evaluation does not assess nonresident (or out-of-state) boats. The fraction of county-registered boats used for manatee viewing in Kings Bay is unknown, as is the number of boats trailered to the area by visitors. As such, the contribution of boats used for manatee viewing cannot be monetized or evaluated in terms of any economic benefit likely to accrue from this rulemaking.

Businesses that benefit both directly and indirectly from manatee viewing can be found in Department of Labor descriptions of Citrus County industries. While these industry descriptions provide useful information about numbers of businesses and the number of individuals they employ, they do not describe the number of businesses and

individuals engaged directly or indirectly in manatee viewing. These industries include: Leisure and hospitality businesses, professional and business services; and trade, transportation, and utility businesses. Through September 2010, there were 288 leisure and hospitality establishments in Citrus County employing 3,294 individuals; 512 professional and business service establishments employing 3,340 individuals; and 683 trade, transportation, and utility establishments employing 7,330 individuals (U.S. Department of Labor 2011).

Improved protection for the manatee may result in an economic benefit to these industries by insuring the continued local presence of viewable manatees and insuring the continued existence of the manatee viewing industry. However, the viability of the local manatee viewing industry, as practiced by both commercial businesses and individuals, is challenged by reported acts of manatee harassment associated with these activities.

Florida waterfront property owners may benefit from manatee protection areas such as the area described in this proposal. Bell and McLean (1997, p. 1) studied the impact of posted manatee speed zones on the property values of waterfront homes in Fort Lauderdale, Broward County, Florida. The authors found a strong relationship between property values and slow-speed zones, and found evidence that slow-speed zones may have a positive impact on home sale price. Slow-speed zones were found to correlate with as much as a 15- to 20-percent increase in sale price. The authors speculated that speed zones may increase property values by reducing noise and fast traffic, and by making it easier for boats to enter and leave primary waterways. In the proposed manatee refuge area, residential property owners may experience these benefits.

In addition, due to reductions in boat wake associated with speed zones, property owners may experience some economic benefits related to decreased costs for maintenance and repair of shoreline stabilization (*i.e.,* seawalls along the water's edge). Similarly, the erosion of shoreline vegetation and aquatic plant communities from boat wakes would lessen, thus improving important fisheries habitat. Speed reductions may also result in increased boater and swimmer safety. These types of benefits cannot be quantified with available information.

Based on previous studies, we believe that this rule would produce some economic benefits. However, given the lack of information available for estimating these benefits, the magnitude of these benefits is unknown.

Economic Impacts

Affected Recreational Activities

For some waterway users, the loss of a local, high-speed watersports area may reduce the quality of these activities or may cause people to forgo the activities. The extra time needed to cross additional slow and/or idle speed areas or to avoid ''no-entry'' areas may inconvenience some recreationists. In this section, we examine the waterborne activities taking place in the area and the extent to which they may be affected by the designation of the proposed manatee refuge. The resulting potential economic impacts are discussed below. Actual impacts cannot be quantified, however, because an actual number of recreationists using the site is not known.

In the proposed Kings Bay Manatee Refuge, affected waterborne activities include traveling, cruising, waterskiing, personal watercraft use, canoeing and kayaking, manatee viewing, snorkeling and diving, and fishing. Based on a recent visitor study that relied on a variety of survey mechanisms, the two most popular activities in Citrus County were manatee viewing and snorkeling and diving (Gold 2008, pp. 4–8). Recreationists engaging in high-speed activities, including waterskiing, use of personal watercraft, and other similar activities would likely experience some impacts due to the proposed regulations; individuals not engaged in high-speed-activities are unlikely to experience much impact due to the proposed regulation.

Primary activities that would be affected by the designation of year-round slow or idle speeds are those that involve high-speed watercraft operations, including waterskiing, which take place between May 1 and August 31 in the watersports area located in the center of Kings Bay. The proposed regulation may cause some water skiers and other recreationists to forgo high-speed activities here, or may reduce the quality of their experience in the event that these recreationists elect to waterski at less preferred alternative sites.

Without data describing the number of affected recreationists and the number of trips that they make every year to the watersports area, costs associated with the loss of this area are unknown. If this information were available, we could estimate the impact of lost or diminished skiing days given the value of a waterskiing day published in the literature. One study by Bergstrom and Cordell (1991, p.67) suggested the lost surplus value may be $ 46.75/day (adjusted to reflect 2002 monetary values) for a day of waterskiing. They applied a multicommunity, multisite travel cost model to estimate demand equations for 37 outdoor recreational activities and trip values, including waterskiing. The analysis was based on nationwide data from the Public Area Recreational Visitors Study collected between 1985 and 1987 and several secondary sources.

Thomas and Stratis (2002, pgs. 30–32) evaluated the effect that reductions in the number of available boating destinations had on recreational boaters in Lee County. Reduced boat speeds at certain sites precluded high-speed activities historically associated with these sites, reducing the number of high-speed destinations available to these boaters. Thomas and Stratis demonstrated that some redistribution of boating trips did subsequently occur and concluded that the reduction in boating destinations resulted in an annual estimated loss per boater of $423.94 in 1996 dollars (or $597.97 when adjusted to reflect 2011 dollar values). The study was conducted in Lee County, not Citrus County, in 1996, and specific locations and 1996 values localize and date the results.

While studies demonstrate that recreationists can experience a change in the quality of their waterborne experience when speeds are restricted in historically high-speed boater destinations, not enough data are available to estimate any losses in economic value that the recreationists who use Kings Bay are likely to experience. However, given that alternative sites are regionally available, economic impacts are not expected to be significant.

Recreationists who transit the designated, summertime slow-speed area would likely experience a diminished quality of the boating experience due to the additional time needed to transit this area at speeds slower than those historically present. These recreationists likely include anglers traveling to downstream fishing sites, and the additional transit times would affect the time that they have available to fish. Lost fishing time could result in catch losses, thereby diminishing the fishing experience. The number of these recreationists and the number of trips that they make is unknown. As a result, the economic cost

of this rulemaking on these individuals is unknown.

Affected Commercial Charter Boat Activities

Various types of charter boats use Citrus County waterways for nature tours and other activities. The number of charter boats using Kings Bay is unknown, and information on their origins and destinations is lacking. However, many charter boats are used by renters to view manatees, an activity that occurs within the refuge area. The refuge designation is unlikely to cause a significant adverse impact to businesses that provide boats for manatee viewing and may even benefit them. Enhanced manatee protection measures should improve the viewing experience and are likely to positively affect this industry. The extra time required for commercial charter boats used for fishing to reach fishing grounds could reduce onsite fishing time and could result in fewer trips. Added travel time may affect the length of a trip, which could result in fewer trips overall, creating a potential economic impact.

Affected Commercial Fishing Activities

Local commercial fisheries may experience some impact due to the proposed regulation. To the extent that the proposed regulation establishes additional speed zones in commercial fishing areas, this may increase transit times associated with the fishing activity, affecting the efficiency of commercial fishing. Costs associated with requirements for the use of manatee-safe float lines would likely increase some fishing gear costs.

Crab boats would have to travel at slower speeds in some locations between crab pots, thereby potentially reducing the number of crabs landed on a daily basis. The speed limits may also slow transit speeds between fishing grounds for both crab and mullet fishing boats. The number of fishing boats operating and the amount of blue crab and mullet landings occurring in areas that would be newly designated speed zones under this proposed rule are unknown. Given this, the impact on the commercial fishing industry cannot be quantified.

Crabbers fishing within the Kings Bay Manatee Refuge would need to modify their gear to ensure that manatees do not become entangled in crab pot float lines. The use of stiffened lines, including lines that incorporate stiffeners (wire, lines enclosed in hose or PVC, *etc.*), crab pot lines to reduce the number of float lines used (where crab pots are strung together and single float lines are used to locate the beginning and end of such a crab pot line), and other methods would increase gear costs. However, the number of crabbers fishing in Kings Bay is unknown, and the extent to which this would impact these users is unknown.

The proposed designation would likely affect commercial fishermen by way of added travel time, which may have an economic impact. However, because added travel times are unlikely to exceed an additional 30 minutes beyond existing travel times, it is unlikely that the proposed rule would result in a significant economic impact on the commercial fishing industry.

Agency Administrative Costs

Agency administrative costs would include costs associated with signposting, enforcement, and some costs for education and outreach to inform the public about new designations within the manatee refuge. The proposed refuge would require nominal, additional signposting activities; however, the number and location of signs needed to post the proposed manatee refuge is not known. Similarly, additional law enforcement and education and outreach needs are anticipated. Associated administrative costs are unknown.

The designation of this manatee refuge would affect less than 530 acres of the State of Florida's 7.5 million acres of waterways and would add restrictions to an already-restricted area to better protect manatees. As a result, the rule would impact the quality of waterborne activity experiences for some recreationists and may lead some recreationists to forgo certain waterborne activities. While the proposed rule would prohibit certain activities within the refuge area, it does not prohibit recreationists from participating in similar activities elsewhere. Alternative sites are available for all waterborne activities that may be affected by this rule. The inconvenience of having to go slower or choose alternative sites for certain waterborne activities would likely have a regional economic cost. While the level of economic benefits that may be attributable to the manatee refuge is unknown (including benefits associated with manatee viewing), these benefits would likely minimize any economic impacts that may be associated with this rule. Given available information, the net economic impact of designating this manatee refuge is not expected to be significant (that is, it would not exceed $100 million per year).

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions) (5 U.S.C. 601 *et seq.*). However, no regulatory flexibility analysis is required if the head of an agency certifies that the rule would not have a significant economic impact on a substantial number of small entities. Thus, for a regulatory flexibility analysis to be required, impacts must exceed a threshold for ''significant impact'' and a threshold for a ''substantial number of small entities.'' See 5 U.S.C. 605(b). SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule would not have a significant economic impact on a substantial number of small entities. This section presents a screening level analysis of the potential effects of the proposed designation of a manatee protection area on small entities. We certify that this rule would not have a significant economic impact on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). An initial/final Regulatory Flexibility Analysis is not required. Accordingly, a Small Entity Compliance Guide is not required.

In order to determine whether the proposed rule would have a significant economic impact on a substantial number of small entities, we utilize available information on the industries most likely to be affected by the designation of the manatee refuge. Small entities likely affected by the proposed rule include entities whose businesses support high-speed recreational boating activities and commercial fishing. However, no current information is available on the specific number of small entities that would potentially be affected. This proposed rule would preclude high-speed activities from an existing summertime water sports area and would add travel time to boating recreationists and commercial activities having to travel through the additional slow-speed zones. Because the only restrictions on recreational activity result from displacement and added travel time and alternative sites are available for all waterborne activities,

we believe that the economic impact on small entities resulting from changes in recreational use patterns would not be significant. The economic impacts on small businesses resulting from this proposed rule are likely to be indirect effects related to reduced demand for goods and services if recreationists choose to reduce their level of participation in waterborne activities. Similarly, because the only restrictions on commercial activity result from the inconvenience of added travel time, we believe that any economic impact on small commercial fishing or charter boat entities would not be significant. Also, the indirect economic impact on small businesses that may result from reduced demand for goods and services from commercial entities is likely to be insignificant.

Small Business Regulatory Enforcement Fairness Act

This proposed rule is not a major rule under 5 U.S.C. 804(2). This proposed rule:

a. Does not have an annual effect on the economy of $100 million or more. As shown above, this proposed rule may cause some inconvenience in the form of displacement and added travel time for recreationists and commercial fishing and charter boat businesses because of speed and access restrictions in this manatee refuge, but it should not translate into any significant business reductions for the many small businesses in Citrus County. Since the only restrictions on recreational activity would result from displacement and added travel time and alternative sites are available for all waterborne activities, we believe that the economic impact on small entities resulting from changes in recreational use patterns would not be significant. The economic impacts on small business resulting from this proposed rule are likely to be indirect effects related to reduced demand for goods and services if recreationists choose to reduce their level of participation in waterborne activities. Similarly, because the only restrictions on commercial activity result from the inconvenience of added travel time, we believe that any economic impact on small commercial fishing or charter boat entities would not be significant. Also, the indirect economic impact on small businesses that may result from reduced demand for goods and services from commercial entities is likely to be insignificant.

b. Would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. It is unlikely that there are unforeseen changes in costs or prices for consumers stemming from this proposed rule. The recreational charter boat and commercial fishing industries may be affected by lower speed limits for some areas when traveling to and from fishing grounds. However, this impact is likely to be limited.

c. Would not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. As stated above, this proposed rule may generate some level of inconvenience to recreationists due to displacement and added travel time, but the resulting economic impacts are believed to be minor and would not interfere with the normal operation of businesses in the affected county. Added travel time to traverse some areas is not expected to be a major factor that would impact business activity.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

a. This proposed rule would not significantly or uniquely affect small governments. A Small Government Agency Plan is not required. The designation of manatee refuges imposes no substantial new obligations on State or local governments.

b. This proposed rule would not produce a Federal mandate of $100 million or greater in any year. As such, it is not a significant regulatory action under the Unfunded Mandates Reform Act.

Takings

In accordance with Executive Order 12630, this proposed rule does not have significant takings implications. A takings implication assessment is not required. The proposed manatee protection area is located over Federal-, State- or privately-owned submerged bottoms. Any property owners in the vicinity would retain navigational access and the ability to maintain their property.

Federalism

In accordance with Executive Order 13132, the proposed rule would not have significant Federalism effects. A Federalism assessment is not required. This proposed rule would not have substantial direct effects on the State, on the relationship between the Federal Government and the State, or on the distribution of power and responsibilities among the various levels of government. We coordinated with the State of Florida to the extent possible on the development of this proposed rule.

Civil Justice Reform

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

Paperwork Reduction Act

This proposed regulation does not contain new collections of information that require approval by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.* The proposed regulation would not impose new recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. OMB has reviewed and approved the information collection requirements associated with special use permits and assigned OMB Control No. 1018–0102. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

We have analyzed this proposed rule in accordance with the criteria of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*). This proposed rule does not constitute a major Federal action significantly affecting the quality of the human environment. An environmental assessment has been prepared and is available for review on-line at *http://www.regulations.gov* (see **ADDRESSES**), or upon request (see **FOR MORE INFORMATION CONTACT**).

Government-to-Government Relationship with Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175 and the Department of the Interior's manual at 512 DM 2, we have evaluated possible effects on Federally recognized Indian Tribes and have determined that there would be no effects.

Energy Supply, Distribution, or Use

On May 18, 2001, the President issued Executive Order 13211 on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Because this proposed rule is not a significant

regulatory action under Executive Order 12866, and it would only require vessels to proceed at slow or idle speeds or avoid no-entry areas in 530 acres of waterways in Florida, it is not expected to significantly affect energy supplies, distribution, and use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Data Quality Act

In developing this proposed rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106–554).

References Cited

For a list of the references cited in this rule, see Docket No. FWS–R4–ES–2011–0079, available at *http://www.regulations.gov*.

Author

The primary author of this document is Jim Valade (see **ADDRESSES**).

Authority

The statutory authority to establish manatee protection areas is provided by the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and record keeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as follows:

PART 17—[AMENDED]

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

Authority: 16 U.S.C 1361–1407; 16 U.S.C 1531–1544; 16 U.S.C 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. Amend § 17.104 by revising paragraph (b) to read as follows:

§ 17.104 Prohibitions.

* * * * *

(b) *Manatee refuge.* It is unlawful for any person within a particular manatee refuge to engage in any waterborne activity which has been specifically prohibited within that refuge, or to engage in any waterborne activity in a manner contrary to that permitted by regulation within that area. Any take of manatees under the Acts (see § 18.3 of this chapter for a definition of ''take'' in regard to marine mammals), including take by harassment, is prohibited wherever it may occur.

* * * * *

3. Amend § 17.108 by:

a. In paragraph (a)(3), removing the period at the end of the paragraph and adding in its place a comma and the words ''to be known as the Magnolia Springs Manatee Sanctuary.'';

b. In paragraph (a)(4), removing the period at the end of the paragraph and adding in its place a comma and the words ''to be known as the Buzzard Island Manatee Sanctuary.'';

c. In paragraph (a)(5), removing the period at the end of the paragraph and adding in its place a comma and the words ''to be known as the Tarpon Springs Manatee Sanctuary.'';

d. In paragraph (a)(6), removing the period at the end of the paragraph and adding in its place a comma and the words ''to be known as the Warden Key Manatee Sanctuary.'';

e. Revising paragraph (b) to read as set forth below; and

f. Adding paragraph (c)(14) to read as set forth below:

§ 17.108 List of designated manatee protection areas.

* * * * *

(b) *Exceptions.* (1) Adjoining property owners, their guests, employees, and their designees may engage in watercraft access and property maintenance activities through manatee sanctuaries (set forth in paragraphs (a)(1) through (a)(11) of this section) and designated ''no entry areas'' in the Kings Bay Manatee Refuge (set forth in paragraph (c)(14) of this section). Use of sanctuary and no-entry area waters is restricted to authorized individuals accessing adjoining properties, storing watercraft, and maintaining property and waterways. Maintenance activities include those actions necessary to maintain property and waterways, subject to any Federal, State, and local government permitting requirements.

(2) Authorized individuals must obtain a sticker or letter of authorization from the Fish and Wildlife Service identifying them as individuals authorized to enter no-entry areas that adjoin their property. Stickers must be placed in a conspicuous location to readily identify authorized watercraft. Individuals with a letter of authorization must have a valid letter in their possession when accessing no-entry areas.

(3) Authorized individuals must conduct any authorized boating activity within these areas at idle or no-wake speeds.

* * * * *

(c) * * *

(14) *The Kings Bay Manatee Refuge.* A tract of submerged land that includes all waters of Kings Bay, including all tributaries and adjoining waterbodies, upstream of the confluence of Kings Bay and Crystal River, described by a line that bears North 53°00′00″ East (True) from the northeasternmost point of an island on the southwesterly shore of Crystal River (approximate latitude 28°53′32″ North, approximate longitude 82°36′23″ West) to the southwesternmost point of a peninsula of Magnolia Shores (approximate latitude 28°53′38″ North, approximate longitude 82°36′16″ West).

(i) *Area covered.* The Kings Bay Manatee Refuge encompasses existing manatee protection areas as described in paragraphs (a)(1) through (a)(7) of this section, and areas outside these sections as depicted on the map in paragraph (c)(14)(ii) of this section.

(ii) *Particular areas.* The following springs fall within the boundaries of the Kings Bay Manatee Refuge. A map showing the entire refuge, including these springs, follows:

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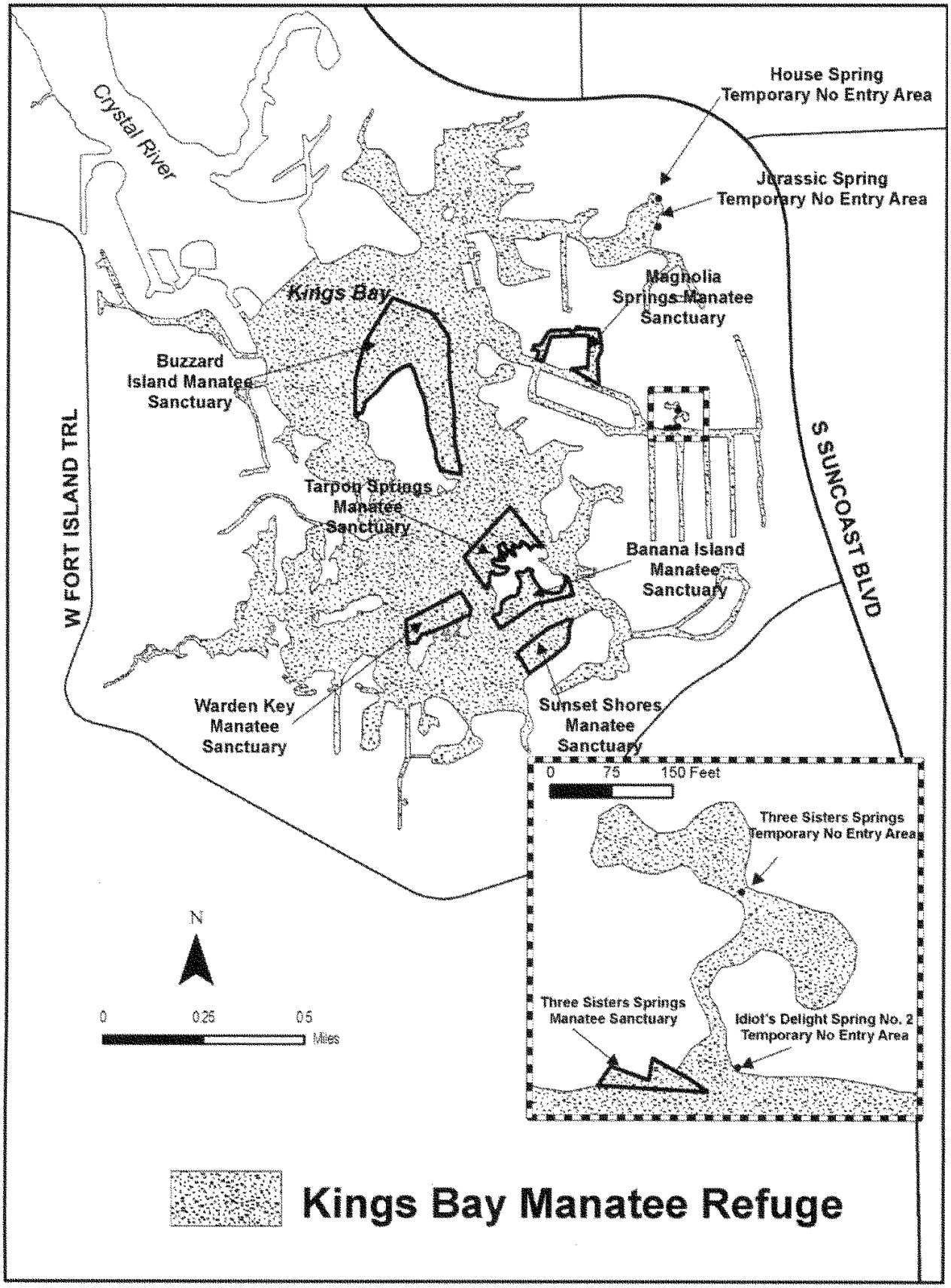

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(A) *Three Sisters Springs.* A tract of submerged land, lying in Section 28, Township 18 South, Range 17 East, Tallahassee Meridian, Citrus County,

Florida, more particularly described as follows: For a point of reference, commence at the northwest corner of said Section 28 in an east southeast direction to the canal that begins on the west side of Southeast Cutler Spur Boulevard and runs west–northwest to Kings Bay. The spring is north and east of the northern terminus of Southeast Paradise Avenue along the northern shore of said canal. Three Sisters Springs includes three main and numerous smaller spring vents and a spring run that connects the vents to said canal in Crystal River, Citrus County, Florida. This area is not the same as set forth in paragraph (a)(7) of this section. This area is behind the sanctuary (north from the mouth of the channel) as set forth in paragraph (a)(7) of this section and no one may enter this area from November 15 through March 31 between the hours of 6:00 p.m. and 7:00 a.m.

(B) *House Spring.* A tract of submerged land, lying in Section 21, Township 18 South, Range 17 East, Tallahassee Meridian, Citrus County, Florida, more particularly described as follows: For a point of reference, commence at the southwest corner of said Section 21 in an east northeast direction to the northeasternmost corner of Hunter Spring Run. The spring is immediately west of and adjacent to Northeast 2nd Court in Crystal River, Citrus County, Florida.

(C) *Jurassic Spring.* A tract of submerged land, lying in Section 21, Township 18 South, Range 17 East, Tallahassee Meridian, Citrus County, Florida, more particularly described as follows: For a point of reference, commence at the southwest corner of said Section 21 in an east northeast direction to the eastern shore of Hunter Spring Run. The spring is immediately west of the western terminus of Bayshore Drive in Crystal River, Citrus County, Florida.

(D) *Idiot's Delight Number 2 Spring.* A tract of submerged land, lying in Section 28, Township 18 South, Range 17 East, Tallahassee Meridian, Citrus County, Florida, more particularly described as follows: For a point of reference, commence at the northwest corner of said Section 28 in an east southeast direction to the canal that begins on the west side of Southeast Cutler Spur Boulevard and runs west–northwest to Kings Bay. The spring is north and east of the northern terminus of Southeast Paradise Avenue along the northern shore of said canal just east of the southern terminus of the Three Sisters Springs run in Crystal River, Citrus County, Florida.

(iii) *Speed restrictions.* Throughout the entire year, watercraft speeds are restricted to slow speed throughout the refuge except in those areas where access is precluded (manatee sanctuaries, no entry areas) or more restrictive speed restrictions are in effect.

(iv) *Time and area prohibitions.* From November 15 to March 31, all waterborne activities, including swimming, diving (including skin and scuba diving), snorkeling, water skiing, surfing, fishing (including with hook and line, by cast net, or spear), and the use of water vehicles (including but not limited to boats powered by engine, wind or other means; ships powered by engine, wind or other means; barges, surfboards, personal watercraft, water skis, and any other devices or mechanisms capable of locomotion on, across, or underneath the surface of the water) are prohibited in areas that are outside of and within specified distances from the existing manatee sanctuaries located in Kings Bay (defined in paragraphs (a)(1) through (a)(7) of this section) and the springs defined in paragraph (c)(14)(ii) of this section: Three Sisters Springs, House Spring, Jurassic Spring, and Idiot's Delight Number 2 Spring.

(v) *Expanded temporary no-entry area.* When manatees exceed the capacity of an existing manatee sanctuary or shift usage around an existing manatee sanctuary or shift usage to Three Sisters Springs, House Spring, Jurassic Spring, and Idiot's Delight Number 2 Spring, due to water or weather conditions, we will designate ''no entry'' areas from November 15 through March 31. Designations of no-entry areas around existing manatee sanctuaries and Three Sisters Springs, House Spring, Jurassic Spring, and Idiot's Delight Number 2 Spring within the Kings Bay Manatee Refuge will be made based on aerial survey observations of manatees using the existing sanctuary sites, current weather information, and other sources of credible, relevant information. We could designate no-entry areas around one or all of the manatee sites in Kings Bay depending on the winter season. We will designate no-entry areas within the Kings Bay Manatee Refuge and outside of existing manatee sanctuaries as follows:

(A) For the sanctuaries set forth in paragraphs (a)(1) through (a)(6) of this section, to a distance not to exceed 100 feet from the existing sanctuary boundary.

(B) For the Three Sisters Springs Sanctuary, to a distance not to exceed 400 feet from the existing boundary. We do not intend to completely mark off the manmade channel. Expansions could occur directly around the existing sanctuary and north into the area locally known as Three Sisters Springs.

(C) For House Spring and Jurassic Spring, an area that does not exceed 100 feet from the associated spring vents.

(D) For Idiot's Delight Number 2 Spring, an area that does not exceed 25 feet from the associated spring vent. Any temporary designation will be configured to avoid the manmade channel in the canal and will not block access into Three Sisters Springs.

(vi) *Temporary no-entry areas.* Temporary no-entry area designations may be made in the existing manatee sanctuaries located in Kings Bay (defined in paragraphs (a)(1) through (a)(7) of this section), Three Sisters Springs, House Spring, Jurassic Spring, and Idiot's Delight Number 2 Spring prior to November 15 and after March 31 during cold fronts when manatees are present. Designations will remain in effect for the duration of a cold front and only when manatees are present; temporary no-entry area designations will remain in effect for no longer than 14 days.

(vii) *Posting of additional protection areas.* Additional protection areas within the Kings Bay Manatee Refuge, but outside of the existing manatee sanctuaries set forth in paragraphs (a)(1) through (a)(7) of this section and around Three Sisters Springs, House Spring, Jurassic Spring, and Idiot's Delight Number 2 Spring, will be posted to distances as described in paragraph (c)(14)(v) of this section and identified by the following devices: buoys, float lines, signs, advisories from onsite Service employees and their designees, or other methods.

(viii) *Notifications.* When waterborne activities pose an immediate threat to aggregations of manatees and are likely to take one or more manatees, additional protection areas outside of existing manatee sanctuaries set forth in paragraphs (a)(1) through (a)(7) of this section and around Three Sisters Springs, House Spring, Jurassic Spring, and Idiot's Delight Number 2 Spring, but within the Kings Bay Manatee Refuge will be posted to distances as described in paragraph (c)(14)(v) of this section. No-entry area designations will occur immediately. We will advise the public of designations through public notice(s) announcing and describing the measures in a local newspaper and other media, including but not limited to, local television and radio broadcasts, Web sites and other news outlets, as soon as time permits. Onsite Service employees and their designees, when

present, may also inform waterway users of designations.

(ix) *Prohibited activities.* We specifically identify and prohibit the activities set forth in this paragraph to prevent the take of manatees by individuals engaged in waterborne activities while in the water, in boats, or on-shore within the Kings Bay Manatee Refuge. In regard to these prohibited activities, we consider a resting manatee to be a mostly motionless manatee on the water bottom, in the water column, or on the water's surface that rises to the surface to breath. While resting, a manatee may make minor changes in its posture and may slightly shift its position. Minor changes in posture occur when resting manatees breathe or roll. Resting manatees may also make slight movements with their flippers or tail to compensate for drift, *etc.* Prohibited activities include:

(A) Chasing or pursuing manatee(s).

(B) Disturbing or touching a resting or feeding manatee(s).

(C) Diving from the surface on to resting or feeding manatee(s).

(D) Cornering or surrounding or attempting to corner or surround a manatee(s).

(E) Riding, holding, grabbing, or pinching or attempting to ride, hold, grab, or pinch a manatee(s).

(F) Poking, prodding, or stabbing or attempting to poke, prod, or stab a manatee(s) with anything, including your hands and feet.

(G) Standing on or attempting to stand on manatee(s).

(H) Separating a mother and calf or attempting to separate a mother and calf.

(I) Separating manatee(s) from a group or attempting to separate manatee(s) from a group.

(J) Giving manatee(s) anything to eat or drink or attempting to give manatee(s) anything to eat or drink.

(K) Actively initiating contact with belted and/or tagged manatee(s) and associated gear, including any belts, harnesses, tracking devices, or antennae.

(L) Interfering with rescue and research activities.

(M) Using mooring and float lines that can entangle manatees.

Dated: June 10, 2011.

Rachel Jacobson,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2011–15603 Filed 6–21–11; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

[Docket No. FWS–R9–MB–2011–0014; 91200–1231–9BPP–L2]

RIN 1018–AX34

Migratory Bird Hunting; Supplemental Proposals for Migratory Game Bird Hunting Regulations for the 2011–12 Hunting Season; Notice of Meetings

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; supplemental.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), proposed in an earlier document to establish annual hunting regulations for certain migratory game birds for the 2011–12 hunting season. This supplement to the proposed rule provides the regulatory schedule, announces the Service Migratory Bird Regulations Committee and Flyway Council meetings, and provides Flyway Council recommendations resulting from their March meetings.

DATES: *Comments:* You must submit comments on the proposed regulatory alternatives for the 2011–12 duck hunting seasons by July 5, 2011. Following subsequent **Federal Register** documents, you will be given an opportunity to submit comments for proposed early-season frameworks by July 29, 2011, and for proposed late-season frameworks and subsistence migratory bird seasons in Alaska by August 31, 2011.

Meetings: The Service Migratory Bird Regulations Committee will meet to consider and develop proposed regulations for early-season migratory bird hunting on June 22 and 23, 2011, and for late-season migratory bird hunting and the 2012 spring/summer migratory bird subsistence seasons in Alaska on July 27 and 28, 2011. All meetings will commence at approximately 8:30 a.m.

ADDRESSES: *Comments:* You may submit comments on the proposals by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R9–MB–2011–0014.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: FWS–R9–MB–2011–0014; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We will not accept e-mailed or faxed comments. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

Meetings: The Service Migratory Bird Regulations Committee will meet in room 200 of the U.S. Fish and Wildlife Service's Arlington Square Building, 4401 N. Fairfax Dr., Arlington, VA.

FOR FURTHER INFORMATION CONTACT: Ron W. Kokel, U.S. Fish and Wildlife Service, Department of the Interior, MS MBSP–4107–ARLSQ, 1849 C Street, NW., Washington, DC 20240; (703) 358–1714.

SUPPLEMENTARY INFORMATION:

Regulations Schedule for 2011

On April 8, 2011, we published in the **Federal Register** (76 FR 19876) a proposal to amend 50 CFR part 20. The proposal provided a background and overview of the migratory bird hunting regulations process, and addressed the establishment of seasons, limits, and other regulations for hunting migratory game birds under §§ 20.101 through 20.107, 20.109, and 20.110 of subpart K. This document is the second in a series of proposed, supplemental, and final rules for migratory game bird hunting regulations. We will publish proposed early-season frameworks in early July and late-season frameworks in early August. We will publish final regulatory frameworks for early seasons on or about August 16, 2011, and for late seasons on or about September 15, 2011.

Service Migratory Bird Regulations Committee Meetings

The Service Migratory Bird Regulations Committee will meet June 22–23, 2011, to review information on the current status of migratory shore and upland game birds and develop 2011–12 migratory game bird regulations recommendations for these species, plus regulations for migratory game birds in Alaska, Puerto Rico, and the Virgin Islands. The Committee will also develop regulations recommendations for September waterfowl seasons in designated States, special sea duck seasons in the Atlantic Flyway, and extended falconry seasons. In addition, the Committee will review and discuss preliminary information on the status of waterfowl.

At the July 27–28, 2011, meetings, the Committee will review information on the current status of waterfowl and develop 2011–12 migratory game bird regulations recommendations for regular waterfowl seasons and other species and

seasons not previously discussed at the early-season meetings. In addition, the Committee will develop recommendations for the 2012 spring/summer migratory bird subsistence season in Alaska.

In accordance with Departmental policy, these meetings are open to public observation. You may submit written comments to the Service on the matters discussed.

Announcement of Flyway Council Meetings

Service representatives will be present at the individual meetings of the four Flyway Councils this July. Although agendas are not yet available, these meetings usually commence at 8 a.m. on the days indicated.

Atlantic Flyway Council: July 21–22, Hotel Viking, Newport, RI.

Mississippi Flyway Council: July 22–23, Crowne Plaza, Little Rock, AR.

Central Flyway Council: July 21–22, Holiday Inn, Cody, WY.

Pacific Flyway Council: July 21, GranTree Inn, Bozeman, MT.

Review of Public Comments

This supplemental rulemaking describes Flyway Council recommended changes based on the preliminary proposals published in the April 8, 2011, **Federal Register**. We have included only those recommendations requiring either new proposals or substantial modification of the preliminary proposals and do not include recommendations that simply support or oppose preliminary proposals and provide no recommended alternatives. Our responses to some Flyway Council recommendations, but not others, are merely a clarification aid to the reader on the overall regulatory process, not a definitive response to the issue. We will publish responses to all proposals and written comments when we develop final frameworks.

We seek additional information and comments on the recommendations in this supplemental proposed rule. New proposals and modifications to previously described proposals are discussed below. Wherever possible, they are discussed under headings corresponding to the numbered items identified in the April 8 proposed rule. Only those categories requiring your attention or for which we received Flyway Council recommendations are discussed below.

1. Ducks

Duck harvest management categories are: (A) General Harvest Strategy; (B) Regulatory Alternatives, including specification of framework dates, season length, and bag limits; (C) Zones and Split Seasons; and (D) Special Seasons/Species Management.

A. General Harvest Strategy

Council Recommendations: The Mississippi Flyway Council recommended that regulations changes be restricted to one step per year, both when restricting as well as liberalizing hunting regulations.

Service Response: As we stated in the April 8 **Federal Register**, the final Adaptive Harvest Management protocol for the 2011–12 season will be detailed in the early-season proposed rule, which will be published in mid-July.

B. Regulatory Alternatives

Council Recommendations: The Mississippi and Central Flyway Councils recommended that regulatory alternatives for duck hunting seasons remain the same as those used in 2010.

Service Response: As we stated in the April 8 **Federal Register**, the final regulatory alternatives for the 2011–12 season will be detailed in the early-season proposed rule, which will be published in mid-July.

C. Zones and Split Seasons

Council Recommendations: The Atlantic Flyway Council recommended allowing States two periods for selecting their zone and split options: spring 2011 for currently offered options, and spring 2012 for possible additional available options.

The Mississippi Flyway Council urged us to provide new options for zones/split-season criteria (*i.e.,* three zones with two splits or four zones) for use during the 2011–12 regulations cycle season (see the April 8 **Federal Register** for a full discussion). They note, however, that some States may not be able to use these new criteria even if they are approved this spring because of their internal regulations setting process. Thus, they request extending the open season for States to select zone/split-season configurations through the 2012 regulations cycle.

The Central and Pacific Flyway Councils recommended extending the current open season for States to select regular season zone/split configurations for 2011–15 through June 2012.

Service Response: As we discussed in the April 8 **Federal Register**, we proposed new guidelines for duck zones and split seasons for use by States in setting their seasons for the 2011–15 hunting seasons. We also prepared a draft Environmental Assessment (EA) on the proposed zone and split season guidelines and provided a brief summary of the anticipated impacts of the preferred alternative with regard to the guidelines. Specifics of each of the four alternatives we analyzed can be found on our Web site at *http://www.fws.gov/migratorybirds,* or at *http://www.regulations.gov*. The comment period on the EA closed on May 15, 2011. We are currently analyzing comments received and determining whether to: (1) Prepare a final EA and Finding of No Significant Impact and authorize [the preferred alternative], (2) reconsider our preferred alternative, or (3) determine that an Environmental Impact Statement should be prepared. We plan to release our final EA and decision in July.

D. Special Seasons/Species Management

ix. Youth Hunt

Council Recommendations: The Atlantic Flyway Council recommended that we remove the criteria for youth hunting days to be two consecutive hunting days and allow the two days to be taken singularly or consecutively outside any regular duck season on a weekend, holidays, or other non-school days when youth hunters would have the maximum opportunity to participate.

x. Mallard Management Units

Council Recommendations: The Central Flyway Council recommends a minor change to the High Plains Mallard Management Unit boundary in Nebraska and Kansas for simplification and clarification.

4. Canada Geese

A. Special Seasons

Council Recommendations: The Atlantic Flyway Council recommended that the 10-day experimental season extension (September 16–25) of the special September Canada goose hunting season in Delaware become operational.

The Central Flyway Council recommended that we increase the daily bag limit framework from five to eight for North Dakota during the special early Canada goose hunting season in September.

The Pacific Flyway Council recommended increasing the daily bag limit in the Pacific Flyway portion of Colorado from three geese to four geese, and increasing the possession limit from six to eight birds during the special September season.

B. Regular Seasons

Council Recommendations: The Mississippi Flyway Council recommended that the framework

opening date for all species of geese for the regular goose seasons in Michigan and Wisconsin be September 16, 2011.

9. Sandhill Cranes

Council Recommendations: The Mississippi Flyway Council recommended a 3-year experimental 30-day sandhill crane season for eastern population sandhill cranes in Kentucky beginning in the 2011–12 season.

The Central and Pacific Flyway Councils recommend using the 2011 Rocky Mountain Population (RMP) sandhill crane harvest allocation of 1,771 birds as proposed in the allocation formula using the 3-year running average for 2008–10. The Councils also recommended the establishment of two new hunting areas for RMP greater sandhill crane hunting in Montana, the addition of Golden Valley County to an existing RMP sandhill crane hunting unit, and the establishment of a new RMP sandhill crane hunting unit in Broadwater County.

The Pacific Flyway Council recommended not allowing a limited hunt for Lower Colorado River Valley (LCRV) Sandhill Cranes in Arizona during the 2011–12 hunting season as survey results indicate the 3-year average population estimate is below the 2,500 birds required by the framework to hunt Lower Colorado River Valley (LCRV) Sandhill Cranes.

14. Woodcock

Council Recommendations: The Atlantic Flyway Council recommended adoption of the ''moderate'' season package of 45 days with a 3-bird daily bag limit in the Eastern Management Unit for the 2011–12 season as outlined in the Interim American Woodcock Harvest Strategy (available at *http://www.fws.gov/migratorybirds/NewsPublicationsReports.html*).

16. Mourning Doves

Council Recommendations: The Atlantic and Mississippi Flyway Councils recommended use of the ''moderate'' season framework for States within the Eastern Management Unit population of mourning doves resulting in a 70-day season and 15-bird daily bag limit. The daily bag limit could be composed of mourning doves and white-winged doves, singly or in combination.

The Mississippi and Central Flyway Councils recommend the use of the standard (or ''moderate'') season package of a 15-bird daily bag limit and a 70-day season for the 2011–12 mourning dove season in the States within the Central Management Unit. The Central Flyway Council also recommended that the opening date for the South Dove Zone in Texas be the Friday before the third Saturday in September.

The Pacific Flyway Council recommended use of the ''moderate'' season framework for States in the Western Management Unit (WMU) population of mourning doves, which represents no change from last year's frameworks. The Council also recommended combining mourning and white-winged dove season frameworks into a single framework, and allowing an aggregate bag in all Pacific Flyway States in the WMU.

18. Alaska

Council Recommendations: The Pacific Flyway Council recommended removal of Canada goose daily bag limit restrictions within the overall dark goose daily bag limit in Units 9, 10, 17, and 18. In these Units, the dark goose limits would be 6 geese per day, with 12 geese in possession.

Public Comments

The Department of the Interior's policy is, whenever possible, to afford the public an opportunity to participate in the rulemaking process. Accordingly, we invite interested persons to submit written comments, suggestions, or recommendations regarding the proposed regulations. Before promulgating final migratory game bird hunting regulations, we will consider all comments we receive. These comments, and any additional information we receive, may lead to final regulations that differ from these proposals.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We will not accept comments sent by e-mail or fax. We will not consider hand-delivered comments that we do not receive, or mailed comments that are not postmarked, by the date specified in the **DATES** section.

We will post all comments in their entirety—including your personal identifying information—on *http://www.regulations.gov*. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov*, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Division of Migratory Bird Management, Room 4107, 4501 North Fairfax Drive, Arlington, VA 22203.

For each series of proposed rulemakings, we will establish specific comment periods. We will consider, but possibly may not respond in detail to, each comment. As in the past, we will summarize all comments we receive during the comment period and respond to them after the closing date in the preambles of any final rules.

Required Determinations

Based on our most current data, we are affirming our required determinations made in the proposed rule; for descriptions of our actions to ensure compliance with the following statutes and Executive orders, see our April 8, 2011, proposed rule (76 FR 19876):

- National Environmental Policy Act;
- Endangered Species Act;
- Regulatory Flexibility Act;
- Small Business Regulatory Enforcement Fairness Act;
- Paperwork Reduction Act;
- Unfunded Mandates Reform Act;
- Executive Orders 12630, 12866, 12988, 13175, 13132, and 13211.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

Authority

The rules that eventually will be promulgated for the 2011–12 hunting season are authorized under 16 U.S.C. 703–711, 16 U.S.C. 712, and 16 U.S.C. 742 a–j.

Dated: June 13, 2011.

Rachel Jacobson,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2011–15599 Filed 6–21–11; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

RIN 0648–BA22

Fisheries of the Northeastern United States; Atlantic Deep-Sea Red Crab; Amendment 3

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

ACTION: Notice of availability of a fishery management plan amendment; request for comments.

SUMMARY: NMFS announces that the New England Fishery Management Council (Council) has submitted Amendment 3 to the Atlantic Deep-Sea Red Crab Fishery Management Plan (FMP) (Amendment 3), incorporating a draft Environmental Assessment (EA) and an Initial Regulatory Flexibility Analysis (IRFA), for review by the Secretary of Commerce. NMFS is requesting comments from the public on Amendment 3, which was developed by the Council to bring the FMP into compliance with the annual catch limit (ACL) and accountability measure (AM) requirements of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Public comments must be received on or before August 22, 2011.

ADDRESSES: A draft EA was prepared for Amendment 3 that describes the proposed action and other considered alternatives, and provides a thorough analysis of the impacts of the proposed measures and alternatives. Copies of Amendment 3, including the draft EA and the IRFA, are available on request from Paul J. Howard, Executive Director, New England Fishery Management Council (Council), 50 Water Street, Newburyport, MA 01950. These documents are also available online at *http://www.nefmc.org.*

You may submit comments, identified by RIN 0648–BA22, by any one of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal: *http://www.regulations.gov.*
- *Fax:* (978) 281–9135, Attn: Moira Kelly.
- *Mail:* Patricia A. Kurkul, Regional Administrator, NMFS, Northeast Regional Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope, ''Comments on Red Crab Amendment 3.''

Instructions: All comments received are part of the public record and will generally be posted to *http://www.regulations.gov* without change. All personal identifying information (for example, name, address, *etc.*) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Moira Kelly, Fishery Policy Analyst, (978) 281–9218; fax: (978) 281–9135.

SUPPLEMENTARY INFORMATION:

Background

The Council developed Amendment 3 with the primary goal of bringing the FMP into compliance with the requirements of the reauthorized Magnuson-Stevens Act. The 2006 reauthorization of the Magnuson-Stevens Act contains several new requirements, including the requirement that all fisheries adopt ACLs to prevent overfishing, and measures to ensure accountability.

In addition to ACLs and AMs for the red crab fishery, Amendment 3 also proposes measures intended to respond to changing conditions in the fishery and opportunities to improve efficiency and accuracy. First, a measure is proposed to replace the days-at-sea (DAS) and a target total allowable catch (TAC) management scheme with a total allowable landings (TAL) limit. Second, a measure is proposed to eliminate the current trip limits for red crab limited access vessels. Third, a measure is proposed to modify the existing trap limit regulations. The current trap limit regulations state that red crab may not be harvested from gear other than a marked red crab trap, no more than 600 traps may be used when fishing for red crab, and lobster, red crab, or fish may not be harvested from a parlor trap while on a red crab DAS. The proposed measure would modify the regulation to prohibit more than 600 traps being deployed in water depths greater than 400 m, prohibit a limited access red crab vessel from harvesting red crab in water depths less than 400 m, and prohibit parlor traps from being deployed at water depths less than 400 m. A fourth measure is proposed to remove the prohibition of landing more than one standard tote (100 lb (45.4 kg)) of female red crabs, conditional on a scientific recommendation from the Council's Scientific and Statistical Committee. Specifications for fishing years 2011–2013 are also proposed.

Public comments on Amendment 3 and its incorporated documents may be submitted through the end of the comment period stated in this notice of availability. A proposed rule to implement Amendment 3 will be published in the **Federal Register** for public comment. Public comments on the proposed rule must be received by the end of the comment period provided in this notice of availability of Amendment 3 to be considered in the approval/disapproval decision on the amendment. All comments received by August 22, 2011, whether specifically directed to Amendment 3 or the proposed rule for Amendment 3, will be considered in the approval/disapproval decision on Amendment 3. Comments received after that date will not be considered in the decision to approve or disapprove Amendment 3. To be considered, comments must be received by close of business on the last day of the comment period.

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

Dated: June 17, 2011.

Margo Schulze-Haugen,

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

[FR Doc. 2011–15639 Filed 6–21–11; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 76, No. 120

Wednesday, June 22, 2011

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Board for International Food and Agricultural Development; Notice of Meeting

Amendment to Original Notice: ''Board for International Food and Agricultural Development; Notice of Meeting'' [FR Doc. 2011–14245 Filed 6–8–11; 8:45 am]

Pursuant to the Federal Advisory Committee Act, notice is hereby given of the public meeting of the Board for International Food and Agricultural Development (BIFAD). The meeting will be held from 8:30 a.m. to 1 p.m. on June 24, 2011 at the National Press Club located at 529 14th St., NW., Washington, DC. ''Higher Education: A Critical Partner in the Feed the Future'' will set the tone for the meeting.

Dr. Brady Deaton, the new Chair of BIFAD, will preside over the proceedings. Dr. Deaton is the Chancellor of the University of Missouri at Columbia.

The announcement of the 2011 World Food Prize Laureate at the State Department on June 21 and the ''Feed the Future'' Research Forum from June 21 to 23 provide the backdrop for the BIFAD public meeting on June 24. The meeting will include the participation of five new BIFAD presidential appointments. Including Dr. Deaton, those new members are Jo Luck, President of Heifer International, Marty McVey of McVey & Company Investments Inc., Gebisa Ejeta, Distinguished Professor, Department of Agronomy, Purdue University and Catherine Bertini, Chair, International Relations Program and Professor, Maxwell School of Citizenship and Public Affairs, Syracuse University. Board members with continuing service include Elsa Murano, Professor and President Emerita of Texas A&M University and William DeLauder, President Emeritus of Delaware State University. After opening remarks by Dr. Deaton, USAID Administrator Rajiv Shah will formally swear in the new Board members and make a short presentation. At the conclusion of Dr. Shah's remarks, Dr. Deaton will acknowledge immediate past Chair Robert Easter and the other outgoing Board members for their service.

The BIFAD Summer public meeting will focus heavily on the USAID Feed the Future (FtF) Initiative. The first session will offer USAID, USDA and Department of Treasury perspectives on the strategic policy considerations for FtF and the implications of the multilateral process. The panel of speakers will include Paul Weisenfeld, Assistant Administrator, Bureau for Food Security; Julie Howard, Deputy Coordinator, Feed the Future; and Lona Stoll, USDA Coordinator, Feed the Future. Elsa Murano, Chair, Department of Agriculture, Texas A&M University and BIFAD member, will serve as respondent and provide university perspectives.

The second FtF session will review outcomes of the Association of Public and Land-grant Universities (APLU)-led consultative process in response to the FtF research strategy. Dr. Montague Demment, Professor of Ecology at University of California-Davis and Associate Vice President for International Development of APLU, will provide an overview of the consultative process for the Board. USAID staff will provide an overview of the research priority outcomes. Because the Collaborative Research Support Programs (CRSPs) are among the major Title XII university-based research programs, Irvin Widders, Director, Dry Grains Pulse CRSP, Michigan State University, will serve as a respondent to address additional issues.

The Board meeting is open to the public, and time will be allotted for a public comment period. The Board benefits greatly in hearing from the stakeholder community and others. To ensure that as many people as possible have the opportunity to contribute to the morning's discussions, comments will be restricted to three minutes for each commenter. At the conclusion of the public comment period, the Board will adjourn the meeting to proceed to an executive luncheon and meeting (closed to the public).

Those wishing to obtain additional information about BIFAD or attend the meeting can refer to the Web site at *http://www.usaid.gov/our_work/agriculture/bifad/,* or contact Susan Owens, Executive Director and Designated Federal Officer for BIFAD. Interested persons may write her in care of the U.S. Agency for International Development, Ronald Reagan Building, Bureau for Food Security, 1300 Pennsylvania Avenue, NW., Room 7.8–061, Washington, DC 20523–2110 or telephone her at (202) 712–0218 or fax (202) 216–3124.

John A. Becker,

Acting USAID Designated Federal Officer for BIFAD, Office of Development Partners, U.S. Agency for International Development.

[FR Doc. 2011–15611 Filed 6–21–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Office of the Secretary

USDA Increases the Domestic Sugar Overall Allotment Quantity, Reassigns Domestic Cane Sugar Allotments, and Increases the Fiscal Year 2011 Raw Sugar Tariff-Rate Quota

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: The Secretary of Agriculture today announced an increase in the domestic sugar Overall Allotment Quantity (OAQ); a reassignment of surplus sugar under domestic cane sugar allotments of 120,000 short tons raw value (STRV) to imports; and an increase in the fiscal year (FY) 2011 raw sugar tariff-rate quota (TRQ) of the same amount.

DATES: *Effective:* June 22, 2011.

FOR FURTHER INFORMATION CONTACT: Angel F. Gonzalez, Import Policies and Export Reporting Division, Foreign Agricultural Service, AgStop 1021, U.S. Department of Agriculture, Washington, DC 20250–1021; or by telephone (202) 720–2916; or by fax to (202) 720–0876; or by e-mail to *angel.f.gonzalez@fas.usda.gov.*

SUPPLEMENTARY INFORMATION: USDA's Commodity Credit Corporation (CCC) today announces an increase in the FY 2011 (October 1, 2010–September 30, 2011) OAQ under the Sugar Marketing Allotment Program to 9,400,000 STRV

and a reassignment of surplus cane sugar allotment to imports. The OAQ was increased due to an increase in estimated sugar demand since the FY 2011 OAQ was established in August 2010. The beet sugar allotment is now 5,108,900 STRV, and the cane sugar allotment is 3,366,100 STRV. The FY 2011 cane sector allotment and cane state allotments after the OAQ increase were larger than could be fulfilled by domestically-produced cane sugar; so the surplus was reassigned to raw sugar imports, as required by law. Upon review of the domestic sugarcane processors' sugar marketing allocations relative to their FY 2011 expected raw sugar supplies, CCC determined that all sugarcane processors had surplus allocation. Therefore, all sugarcane states' sugar marketing allotments are reduced with this reassignment. The new cane state allotments are Florida, 1,464,666 STRV; Louisiana, 1,526,050 STRV; Texas, 147,138 STRV; and Hawaii, 228,246 STRV. The FY 2011 sugar marketing allotment program will not prevent any domestic sugarcane processors from marketing all of their FY 2011 sugar supply.

On August 5, 2010, USDA established the FY 2011 TRQ for raw cane sugar at 1,231,497 STRV (1,117,195 metric tons raw value, MTRV*), the minimum to which the United States is committed under the World Trade Organization (WTO) Uruguay Round Agreements. On April 11, 2011, USDA announced a reassignment of surplus sugar under domestic cane sugar allotments of 325,000 STRV (294,835 MTRV) to imports, and increased the FY 2011 raw sugar TRQ by the same amount. Pursuant to Additional U.S. Note 5 to Chapter 17 of the U.S. Harmonized Tariff Schedule (HTS) and Section 359k of the Agricultural Adjustment Act of 1938, as amended, the Secretary of Agriculture today further increased the quantity of raw cane sugar imports of the HTS subject to the lower tier of duties during FY 2011 by 120,000 STRV (108,862 MTRV). With this increase, the overall FY 2011 raw sugar TRQ is now 1,676,497 STRV (1,520,892 MTRV). Raw cane sugar under this quota must be accompanied by a certificate for quota eligibility and may be entered under subheading 1701.11.10 of the HTS until September 30, 2011. The Office of the U.S. Trade Representative will allocate this increase among supplying countries and customs areas.

This action is being taken after a determination that additional supplies of raw cane sugar are required in the U.S. market. USDA will closely monitor stocks, consumption, imports and all sugar market and program variables on an ongoing basis, and may make further program adjustments during FY 2011 if needed.

* Conversion factor: 1 metric ton = 1.10231125 short tons.

Dated: June 16, 2011.

Michael T. Scuse,

Acting Under Secretary, Farm and Foreign Agricultural Services and Acting President, Commodity Credit Corporation.

[FR Doc. 2011–15521 Filed 6–21–11; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Intent To Grant Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of intent.

SUMMARY: Notice is hereby given that the U.S. Department of Agriculture, Agricultural Research Service, intends to grant to New Varieties Development & Management Corporation of Lakeland, Florida, an exclusive license to the variety of citrus claimed in U.S. Plant Patent Application Serial No. 12/931,765, ''Mandarin Tree Named US Early Pride,'' filed on February 10, 2011.

DATES: Comments must be received on or before July 22, 2011.

ADDRESSES: Send comments to: USDA, ARS, Office of Technology Transfer, 5601 Sunnyside Avenue, Rm. 4–1174, Beltsville, Maryland 20705–5131.

FOR FURTHER INFORMATION CONTACT: June Blalock of the Office of Technology Transfer at the Beltsville address given above; *telephone:* 301–504–5989.

SUPPLEMENTARY INFORMATION: The Federal Government's rights in this plant variety are assigned to the United States of America, as represented by the Secretary of Agriculture. It is in the public interest to so license this variety as New Varieties Development & Management Corporation of Lakeland, Florida has submitted a complete and sufficient application for a license. The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published Notice, the Agricultural Research Service receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Richard J. Brenner,

Assistant Administrator.

[FR Doc. 2011–15468 Filed 6–21–11; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Economic Research Service

Notice of Intent to Request New Information Collection

AGENCY: Economic Research Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to send comments regarding any aspect of this proposed information collection. This is a new collection for the Rural Establishment Innovation Survey.

DATES: Written comments on this notice must be received on or before August 22, 2011 to be assured of consideration.

ADDRESSES: Address all comments concerning this notice to Tim Wojan, Resource and Rural Economics Division, Economic Research Service, U.S. Department of Agriculture, 1800 M St., NW., Room N4110, Washington, DC 20036–5801. Comments may also be submitted via fax to the attention of Tim Wojan at 202–694–5756 or via e-mail to *twojan@ers.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the office of the Economic Research Service during regular business hours (8:30 a.m. to 5 p.m., Monday through Friday) at 1800 M St., NW., Room N4110, Washington, DC 20036–5801.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments and replies will be a matter of public record. 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 those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: For further information contact Tim Wojan at the address in the preamble. Tel. 202–694–5419.

SUPPLEMENTARY INFORMATION:

Title: Rural Establishment Innovation Survey.

OMB Number: 0536–XXXX.

Expiration Date: Three years from the date of approval.

Type of Request: New collection.

Abstract: This survey of business establishments, funded through USDA's Rural Development Mission Area, will be conducted over a 6-month period with up to 30,000 respondents to collect information on rural tradable business sectors such as manufacturing and professional services. This information will contribute to a better understanding of how rural businesses and their communities are dealing with the increasing competitive pressures and opportunities associated with the spread of new information technologies through our economy and the business and community characteristics associated with effective response to these pressures and opportunities. This information is critical to the Rural Development Mission Area's aim of creating jobs, developing new markets and increasing competitiveness for rural businesses and communities.

The information to be collected by the Rural Establishment Innovation Survey is necessary to understand: (1) The adoption of innovative practices and their contribution to firm productivity; (2) the availability and use of local and regional assets (such as workforce education, local financial institutions, strong local business and other economic associations, and transportation infrastructure) and the association of these assets with successful adjustment; and (3) the extent and importance of participation in Federal, State and local programs designed to promote rural business vitality and growth. This need is made more urgent by increased international competition in goods and some service markets, particularly from low labor cost countries. The traditional cost advantage of domestic rural establishments has been significantly eroded by these developments, requiring emphasis on new products, new processes, new marketing channels and improved customer service. A thorough understanding of the viability of the rural business sector requires collecting information on the capability for innovation.

As the first collection of information devoted specifically to innovation in rural business establishments, the proposed survey will complement other Federal efforts in gauging innovative activity in the private sector. Information on formal research and development (R&D) activities is collected by the National Science Foundation using the Business R&D and Innovation Survey. While some of this formal research and development activity takes place in nonmetropolitan counties, it is anticipated that the great majority of rural innovation occurs less through the creation of new patentable products than through the adoption of new practices and niche marketing. The emphasis of the proposed collection will be on understanding the process of innovation in business establishments as opposed to measuring R&D inputs.

Another difference between this and other Federal surveys on innovative activity will be the focus on constraints to innovation stemming from nonmetropolitan locations. Information on the availability of skilled workers and the ability to recruit managers and professionals will inform possible human capital impediments to innovation. Information on access to credit needed for business formation and development will allow for assessing financing impediments to innovation. Information on the availability of broadband Internet service and how this capability affects business strategy will allow assessing infrastructure impediments to innovation. Information on interaction with suppliers, customers, competitors, business associations and other local institutions providing real services to the establishment will inform the importance of regional clusters to innovation.

The survey will collect data from about 30,000 business establishments in tradable sectors that will include mining, manufacturing, wholesale trade, transportation and warehousing, information, finance and insurance, professional/scientific/technical services, arts, and management of businesses. Only businesses with 5 or more employees will be included in the sample. While the focus of the survey will be on establishments in nonmetropolitan counties, establishments from metropolitan counties will be sampled in adequate numbers to allow comparative analysis. Businesses will be selected at random from strata defined by establishment size categories, industry and metropolitan or nonmetropolitan status of the county. The sample will be selected from the business establishment list maintained by state employment security departments where state approval is granted, and from a proprietary business establishment list frame for those states where approval is not granted. The much more comprehensive coverage of new and small establishments available in state administrative data provides a compelling argument for this hybrid sample frame approach, as these establishments are critical to examining processes of entrepreneurship and innovation.

The interview protocol will include a screening interview to identify the most knowledgeable person in the establishment to respond to questions regarding innovative activities of the entity. Screening greatly improves the quality and effectiveness of the contact information. The most appropriate phone number, e-mail address and mailing address will be collected at this time to allow efficient distribution of a multi-modal survey instrument to the most appropriate respondent for the business. Respondents will have the flexibility to respond to a Web questionnaire, a mail questionnaire, or a telephone survey based on their personal preference. This protocol will reduce respondent burden by using the survey mode which is most efficient for a given respondent. Past research has demonstrated that multi-modal surveys also increase survey response rates. A limited number of control surveys will be used to assess any mode bias.

Social exchange theory will also be invoked as this is seen as integral to the tailored design methodology (Dillman et al., 2009) that will be employed in this study to increase response rate. In addition to offering mixed survey modes, the design will integrate multiple and mutually supportive ways to appeal to the diversity of respondents in this business population. The following are some examples of these design elements:

- The survey request will be distinguishable from other surveys and will emphasize how the information will be used and describe the benefits back to the population for responding to the survey.
- Survey appeals in contacts will show positive regard and call on the norms of social responsibility by asking for respondents' help and advice as some respondents feel rewarded when they know they have helped others.

• Survey contacts will be personally addressed, toll free numbers will be provided for answering questions and providing help. Confidentiality of responses will be ensured and respondents will know how to contact the surveyor if they have questions on security or other issues.

• All contacts will be personalized and will emphasize why the study is important and express appreciation for respondents' help. They will be formally thanked for promptly completing questionnaires.

• Small tangible token rewards provided in advance and at the time of the survey request will be further tested with small businesses to encourage response. Previous survey research has shown that small cash token incentives provided with the survey significantly increase response rates and do much better than promised rewards or nonmonetary rewards.

A key component of tailored survey design is considering and balancing how features of questions, questionnaires, mailings, interviewing, and the context of the survey will influence trust, cost, and rewards associated with the survey circumstances and respondents.

All study instruments will be kept as simple and respondent-friendly as possible. Responses are voluntary and confidential. Responses will be used to produce statistics and for no other purpose. Data files from the survey will not be released to the public.

Affected Public: Respondents include business establishments with at least 5 employees in both nonmetropolitan and metropolitan counties.

Estimated Number of Respondents: The survey is cross-sectional and will be completed at one point in time. The survey will have a complex mixed survey administration to include telephone screening, pre-notification letter with Web access, multi-contact telephone interviewing, follow-up nonrespondent mail questionnaires, and simultaneous Web questionnaires offered during all contacts. Completion time for each questionnaire, based on comparisons with similar mixed modes is estimated at 30 minutes per completion, including time for reading correspondence, returning an eligibility postcard or responding to a screening call, reviewing instructions, gathering data needed, and responding to questionnaire items. It is also expected that those choosing not to participate will require 10 minutes to review the materials and decide not to participate.

Full Study: The initial sample size for the full study is 30,000 businesses. The expected overall response rate is 80 percent for firms in the main study. The total estimated response burden for all of those participating in the study is 12,000 hours (30,000 respondents × 80 percent response rate × 0.50 hours) and for the non-responding business is 1,000 hours (6000 respondents × 10 minutes).

Pilot Study: A pilot test of the survey will be done in advance of the full study survey. The purpose of the pilot is to evaluate the survey protocol, and test instruments and questionnaires. The initial sample size for this phase of the research is 4,000 businesses. The expected response rate is 80% of firms. The total estimated response burden for the pilot testing is 1,600 hours (4,000 respondents × 80 percent × 0.5 hours). Non-responding businesses will experience 133 hours of burden (800 respondents × 10 minutes). Total respondent burden is estimated at 14,733 hours (see table below).

Testing will be limited to a maximum of 9 businesses which will be consulted on the questionnaire and asked to complete the questionnaire in a cognitive interview test.

ESTIMATED RESPONDENT BURDEN FOR RURAL ESTABLISHMENT INNOVATION SURVEY

Survey	Sample Size	Freq	Responses				Non-Response				Total burden hours
			Resp. Count	Freq. × Count	Min./ Resp.	Burden Hours	Nonresp Count	Freq. × Count	Min./ Nonr.	Burden Hours	
Pilot Study	4,000	1	3,200	3,200	30	1,600	800	800	10	133	1,733
Pilot Study	30,000	1	24,000	24,000	30	12,000	6,000	6,000	10	1,000	13,000
Total	34,000					13,600				1,133	14,733

Dated: May 9, 2011.

Katherine R. Smith,

Administrator, Economic Research Service.

[FR Doc. 2011–15474 Filed 6–21–11; 8:45 am]

BILLING CODE 3410–18–P

DEPARTMENT OF AGRICULTURE

Forest Service

Rangeland Allotment Management Planning on the Fall River and Oglala Geographic Areas, Pine Ridge Ranger and Fall River Ranger Districts, Nebraska National Forest, Nebraska and South Dakota

AGENCY: Forest Service, USDA.

ACTION: Request for an extension of the proposed environmental impact statement.

SUMMARY: We are requesting an extension of the proposed EIS for the USDA Forest Service Rangeland Allotment Management Planning on the Fall River West Geographic Area of the Fall River Ranger District and the Oglala Geographic Area of the Pine Ridge Ranger District, Nebraska National Forest. Our initial Notice of Intent was published in Vol. 75, No. 112 Friday, June 11, 2010.

The USDA, Forest Service, will prepare an environmental impact statement (EIS) analyzing the management of rangeland vegetation resources, which includes livestock grazing, on the National Forest System (NFS) lands within the Oglala Geographic Area (OGA) of the Oglala National Grassland on the Pine Ridge Ranger District and the West Geographic Area (WGA) of the Buffalo Gap National Grassland on the Fall River Ranger District of the Nebraska National Forest (Analysis Area) areas as mapped by the 2001 Nebraska National Forest Revised Land and Resource Management Plan (Forest Plan). A Notice of Intent (NOI) for this project was published June 11, 2010 (75 No. 112 FR 33239–33241). This revised NOI is being issued to update the project schedule. There will be a record of decision (ROD) for each geographic area.

Proposed management actions would be implemented beginning in the year 2013. The agency gives notice of the full environmental analysis and decision-making process that will occur on the proposal so interested and affected people may become aware of how they may participate in the process and contribute to the final decision.

DATES: Comments concerning the scope of the analysis were received by July 30, 2010. The initial scoping period has

been completed. The draft environmental impact statement is expected [January 2012] and the final environmental impact statement is expected [July 2012].

FOR FURTHER INFORMATION CONTACT: For further information about the Oglala Geographic Area on the Oglala National Grassland call Lora O'Rourke, Co-Interdisciplinary Team Leader, at 308–432–0300. For further information about the West Geographic Area on the Buffalo Gap National Grassland, call Robert Novotny, Co-Interdisciplinary Team Leader at 605–745–4107.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Vegetation resources on approximately 94,174 acres of NFS lands lying within the Oglala National Grassland in Sioux and Dawes Counties of northwest Nebraska, and approximately 117,548 acres of NFS lands lying within the Buffalo Gap National Grassland in Fall River County of southwest South Dakota, are being analyzed to determine if and how existing conditions differ from desired conditions outlined in the 2001 Nebraska National Forest Land and Resource Management Plan (Forest Plan).

Vegetation in the Analysis Area is characteristic of mixed-grass prairie and lesser amounts of ponderosa pine/juniper habitats. Short-grass species include blue grama, buffalograss, and upland sedges. Mid-grass species include western wheatgrass, green needlegrass, and to a lesser extent sideoats grama. Shrubs include Wyoming big sagebrush, greasewood, and yucca glauca. Some creeks transverse the area and support plains cottonwood, green ash, and willow.

A large portion of the Analysis Area evolved under a history of homesteading in the early twentieth century, and a prolonged drought period combined with the economic depression of the late 1920's and early 1930's caused many of these homesteads to fail. Starting in the 1930's, land was purchased through northwestern Nebraska and southwestern South Dakota under the Land Utilization Project initiated by the Agricultural Adjustment Administration. This continued with the Bankhead Jones Farm Tenant Act of 1937, which was designed to develop a program of land conservation. Administration of these lands was turned over to the Soil Conservation Service the following year and transferred to the United States Forest Service in 1954.

Today the Oglala and Buffalo Gap National Grasslands support and provide a variety of multiple resource uses and values. Livestock ranching operations in the area depend on National Grassland acreage to create logical and efficient management units. Cattle and sheep, in accordance with 10-year term and/or annual temporary livestock grazing permits, are currently authorized to graze the allotments within the Analysis Area. In order to determine how existing resource conditions compare to desired conditions, data from monitoring and analysis (historical and present) will be used. During the past 5–7 years, drought conditions have impacted plant vigor, canopy, and litter cover in most parts of the Analysis Area.

Purpose and Need for Action: The purpose of this project is to determine if livestock grazing will continue to be authorized on all, none, or portions, of the 41 allotments in the Fall River West GA and the 35 allotments in the Oglala GA. And if livestock grazing is to continue, how to best maintain or achieve desired conditions and meet forest plan objectives, standards and guidelines. The action is needed to ensure that the project areas are meeting forest plan desired conditions for plant species composition, vegetation structure, and habitat for sharp-tailed grouse, sage grouse, black-tailed prairie dog (management indicator species) and swift fox (r2 sensitive species). There is also a need to review existing livestock management strategies and, if necessary, update them to implement 2001 Forest Plan direction and meet the requirements of section 504 of Public Law 104–19 (Rescissions Act, signed 7/27/95). The 2001 Forest Plan states that livestock grazing may occur as one of the multiple uses on the Nebraska National Forest, consistent with standards and guidelines. Livestock grazing is currently occurring in the analysis area under the direction of existing Allotment Management Plans (AMPs) and through direction provided in annual operating instructions (AOIs). The results of this analysis may require issuing or modifying grazing permits and AMPs including reductions of permitted livestock numbers and/or modifications of the grazing season. Modifications would be documented in updated term grazing permits and/or grazing agreements and associated AMPs for the allotments.

The Forest Plan identifies lands within the OGA and FRWGA as containing lands that are capable and suitable for grazing by domestic livestock. These lands are to be monitored to evaluate both implementation and effectiveness of management actions.

In all cases, vegetation management tools will be used that meet Forest Plan objectives, standards, and guidelines and that will maintain or move existing resource conditions toward desired conditions for that geographic area. If monitoring indicates that practices are being properly implemented and that resource trends are moving toward meeting desired conditions in a timely manner, management may continue unchanged. If monitoring indicates that there is a need to modify management practices, adaptive options as analyzed in the EIS will be selected and implemented.

Consultation with the U.S. Fish and Wildlife Service, as required by the Endangered Species Act (ESA), will be completed on all proposed activities.

An interdisciplinary team has been selected to do the environmental analysis, as well as prepare and accomplish scoping and public involvement activities.

Possible Alternatives: Potential alternatives include:

1. No action, No change from authorized grazing use or current situation.
2. No Grazing.
3. Livestock grazing incorporating adaptive management to meet the Forest Plan goals, objectives, standards, and guidelines.

Responsible Officials: District Ranger at the Pine Ridge Ranger District, 125 North Main Street, Chadron, Nebraska 69337; and Michael E. McNeill, District Ranger at the Fall River Ranger District, 1801 Highway 18 Truck Bypass, Hot Springs, South Dakota 57747–0732 are the Responsible Officials for making the decision on this action. They will document their decision and rationale in a Record of Decision.

The Responsible Officials will consider the results of the analysis and its findings and then document their decisions in two separate Records of Decision (ROD), one for the OGA and one for the FRWGA. The decisions will determine whether or not to authorize livestock grazing on all, part, or none of the Analysis Area, and if so, what adaptive management design criteria, adaptive options, and monitoring will be implemented so as to meet or move toward the desired conditions as specified in the Forest Plan.

Nature of Decision To Be Made: The EIS is not a decision document. The purpose of the EIS document is to disclose the direct, indirect, and cumulative effects of the proposed

action and other alternatives that are analyzed. After providing the public an opportunity to comment on the specific activities described in the alternatives, the Responsible Officials will review all alternatives and the anticipated environmental consequences of each in order to make the following decisions:

• Whether or not to authorize livestock grazing within the Analysis Area in whole or in part.

• If grazing is to be Authorized, (a) what grazing systems and prescribed livestock use would be implemented; (b) what structural and non-structural range improvements would be necessary; and (c) what type of monitoring program would be proposed.

• If necessary, identify any ''mitigation measure(s)'' needed to implement the decision.

Individual Allotment Management Plans (AMPs) would then be developed to incorporate conditions outlined in the Record of Decision. These AMPs will become part of each associated term permit and/or grazing agreement issued.

Public Scoping Process: Comments and input regarding this proposal were requested from the public, other groups and agencies via direct mailing on March 10, 2008. Comments received during this first scoping process have been made part of the project record and will be addressed in the analysis process. With this second revised NOI, additional comments were received by July 30, 2010. Anyone who has provided comments to the draft EIS or expressed interest during the two comment periods will have standing in the process.

Public involvement will be especially important at several points during the analysis, beginning with the scoping process. The Forest Service will seek information, comments, and assistance from Federal, State, local agencies, Tribes, and other individuals or organizations that may be interested in, or affected by, the proposal. The scoping activities will include: (1) Engaging potentially affected or interested parties by written correspondence, (2) contacting those on our Forest media list, and (3) hosting public information meeting(s).

Preliminary Issues

Effects of proposed management strategies on natural ecosystems. This includes elements such as native and desirable nonnative plant and animal communities; black-tailed prairie dog management; riparian areas; upland grasslands; wooded draws; ponderosa pine forested areas; areas of hazardous fuels; and threatened, endangered, sensitive, and management indicator species. Social-economic effects (positive or negative) on livestock grazing permittees and the local economy from changes in livestock management. Effects of proposed livestock grazing strategies on recreational activities and/or experiences.

Comment Requested: The notice of intent published on June 11, 2010, initiated the formal scoping process that guides the development of the environmental impact statement. Initial public comments were due and have been received by July 30, 2010.

Early Notice of Importance for Public Participation in Subsequent Environmental Review: A draft environmental impact statement (DEIS) will be prepared for comment. The comment period on the draft environmental impact statement will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC, 435 U.S. 519, 553 (1978).* Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

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

Comments received, including the names and addresses of those who comment, will be considered part of the public record on this proposal and will be available for public inspection.

Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21.

Dated: June 15, 2011.

Jane D. Darnell,

Forest Supervisor.

[FR Doc. 2011–15572 Filed 6–21–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Plumas County Resource Advisory Committee (RAC)

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Plumas County Resource Advisory Committee (RAC) will hold a meeting on July 8, 2011 in Quincy, CA. The purpose of the meeting is to review applications for Cycle 11 funding and select projects to be recommended to the Plumas National Forest Supervisor for calendar year 2012 funding consideration. The funding is made available under Title II provisions of the Secure Rural Schools and Community Self-Determination Act of 2000.

DATES AND ADDRESSES: The meeting will take place from 9–1:30 at the Mineral Building-Plumas/Sierra County Fairgrounds, 208 Fairgrounds Road, Quincy, CA.

FOR FURTHER INFORMATION CONTACT: (or for special needs): Lee Anne Schramel Taylor, Forest Coordinator, USDA, Plumas National Forest, P.O. Box 11500/159 Lawrence Street, Quincy, CA 95971; (530) 283–7850; or by e-mail *eataylor@fs.fed.us.* Other RAC information may be obtained at *http://www.fs.fed.us/srs.*

Dated: June 15, 2011.

Matt Janowiak,

Acting Deputy Forest Supervisor.

[FR Doc. 2011–15542 Filed 6–21–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Meeting; Federal Lands Recreation Enhancement Act (Title VIII, Pub. L. 108–447)

AGENCY: Rocky Mountain Region, USDA Forest Service.

ACTION: Notice of Meeting.

SUMMARY: The Colorado Recreation Resource Advisory Committee will tentatively meet in Denver, CO. The purpose of the meeting is to train the new committee members and provide them with the information they need to be effective committee members and review several fee proposals. These fee proposals will tentatively include:

1. A new fee for the North Fruita Desert Campground located in the Grand Junction Field Office Area of the BLM.
2. An increase of fees for the Shelf Road Recreation Area in the Royal Gorge Field Office of the BLM.
3. An increase of overnight camping fees for the Penitente Canyon Campground located in the San Luis Valley Public Lands Center area.
4. A new fee for overnight camping fees at the new Zapata Falls Campground located in the San Luis Valley Public Lands Center area.
5. A fee revision for the Green Mountain Reservoir recreation area. Located on the Dillon Ranger District of the White River National Forest.

DATES: The meeting will be held July 12–13, 2011 from 9 a.m.–4:30 p.m. This meeting will be held only if a quorum of eight members is present.

ADDRESSES: The meeting will be at the American Mountaineering Center, 710 10th Street, Golden, CO. Send written comments to Steve Sherwood, Designated Federal Official, 740 Simms Street, Golden, CO 80401 or *ssherwood@fs.fed.us.*

FOR FURTHER INFORMATION CONTACT: Pam DeVore, Colorado Recreation Resource Advisory Committee Coordinator, at 303–275–5043 or *pdevore@fs.fed.us.*

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Committee discussion is limited to Forest Service, Bureau of Land Management staff and Committee members. Persons who wish to bring recreation fee matters to the attention of the Committee may file written statements with the Committee staff. Written comments received at least a week before the meeting will be available for committee review. Written comments received less than a week before the meeting may not be available for committee referral. There will be time on the agenda for verbal comments and the Chairperson may ask for comments from the public at any time during the meeting. All persons wishing to address the committee must sign in at the door.

Check for the status of the meeting, the final agenda and a final list of the fee proposals to be reviewed at: *http://www.fs.usda.gov/goto/r2/recreation/rac.*

The Recreation RAC is authorized by the Federal Land Recreation Enhancement Act, which was signed into law by President Bush in December 2004.

Dated: June 14, 2011.

Maribeth Gustafson,

Deputy Regional Forester, Operations.

[FR Doc. 2011–15550 Filed 6–21–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request Approval To Revise and Extend an Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intent of the National Agricultural Statistics Service (NASS) to request revision and extension of a currently approved information collection, the Livestock Slaughter Survey. Revision to burden hours may be needed due to changes in the size of the target population, sampling design, and/or questionnaire length.

DATES: Comments on this notice must be received by August 22, 2011 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–0005, by any of the following methods:

- *E-mail: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *Fax:* (202) 720–6396.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: NASS Clearance Officer, U.S. Department of Agriculture, Room 5336A, Mail Stop 2024, South Building, 1400 Independence Avenue, SW., Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: NASS Clearance Officer, U.S. Department of Agriculture, Room 5336A, South Building, 1400 Independence Avenue SW., Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Joseph T. Reilly, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–4333.

SUPPLEMENTARY INFORMATION:

Title: Livestock Slaughter Survey.

OMB Control Number: 0535–0005.

Approval Expires: November 30, 2011.

Type of Request: To revise and extend a currently approved information collection for a period of three years.

Abstract: The primary objective of the National Agricultural Statistics Service is to prepare and issue State and national estimates of crop and livestock production, prices, and disposition as well as economic statistics, farm numbers, land values, on-farm pesticide usage, pest crop management practices, as well as the Census of Agriculture. Livestock slaughter data are used to estimate U.S. red meat production and reconcile inventory estimates which provide producers and the rest of the industry with current and future information on market supplies. This data is also used in preparing production, disposition, and income statistics which facilitate more orderly production, marketing, and processing of livestock and livestock products.

Authority: These data will be collected under the authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3501, *et seq.*) and Office of Management and Budget regulations at 5 CFR part 1320.

NASS also complies with OMB Implementation Guidance, ''Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA),'' **Federal Register**, Vol. 72, No. 115, June 15, 2007, p. 33362.

Estimate of Burden: The Livestock Slaughter Survey includes a weekly survey of 900 Federally Inspected (FI) slaughter plants and monthly/quarterly surveys of approximately 1,950 Non-Federally Inspected (NFI) slaughter facilities. Public reporting burden for this collection of information is estimated to average 10 to 15 minutes per response for an estimated annual burden of 3,335 hours. (The USDA inspectors are not included in the

calculation of total burden, since they are Federal employees and are performing this task as a part of their job functions.)

Respondents: Farmers, USDA inspectors, and custom/state inspected slaughter plants.

Estimated Number of Respondents: 2,850.

Estimated Total Annual Burden on Respondents: 3,335 hours.

Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at (202) 690–2388 or at *ombofficer@nass.usda.gov.*

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, technological or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, May 23, 2011.

Joseph T. Reilly,

Associate Administrator.

[FR Doc. 2011–15476 Filed 6–21–11; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–802]

Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Extension of Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''Department'') is extending the time limits for the final results of the administrative review of certain frozen warmwater shrimp from the Socialist Republic of Vietnam (''Vietnam''). The review covers the period February 1, 2009, through January 31, 2010.

DATES: *Effective Date:* June 22, 2011.

FOR FURTHER INFORMATION CONTACT: Susan Pulongbarit, Paul Walker, or Jerry Huang, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–4031, (202) 482–0413, or (202) 482–4047, respectively.

Background

On April 9, 2010, the Department published in the **Federal Register** a notice of initiation of the administrative reviews of the antidumping duty orders on certain frozen warmwater shrimp from Vietnam and the People's Republic of China. *See Notice of Initiation of Administrative Reviews and Requests for Revocation in Part of the Antidumping Duty Orders on Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam and the People's Republic of China,* 75 FR 18154 (April 9, 2010). On March 4, 2011, the Department published the preliminary results of the review of shrimp from Vietnam. *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Preliminary Results, Partial Rescission, and Request for Revocation, In Part, of the Fifth Administrative Review,* 76 FR 12054 (March 4, 2011). The final results are currently due no later than July 5, 2011.

Statutory Time Limits

In antidumping duty administrative reviews, section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act''), requires the Department to make a final determination in an administrative review of an antidumping duty order within 120 days after the date on which the preliminary results are published. However, if it is not practicable to complete the review within this time period, section 751(a)(3)(A) of the Act allows the Department to extend the 120 day period to 180 days after the preliminary results if it determines it is not practicable to complete the review within the foregoing time period.

Extension of Time Limit for Preliminary Results of Review

We determine that it is not practicable to complete the final results of this administrative review within the 120 day time limit because the Department requires additional time to analyze issues in case and rebuttal briefs submitted by parties, including comments on surrogate country selection, wage rate calculation, and shrimp surrogate value.

Therefore, in accordance with section 751(a)(3)(A) of the Act, the Department is extending the time period for completion of the final results of this review, which is currently due on July 5, 2011, by 45 days to 165 days after the date on which the preliminary results were published. Therefore, the final results are now due no later than August 16, 2011.

We are issuing and publishing this notice in accordance with sections 751(a)(3)(A) and 777(i) of the Act.

Dated: June 15, 2011.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2011–15647 Filed 6–21–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–421–811]

Purified Carboxymethylcellulose from the Netherlands; Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to requests from petitioner Aqualon Company, a unit of Hercules Incorporated and a U.S. manufacturer of purified carboxymethylcellulose, and Akzo Nobel Functional Chemicals B.V., the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on purified carboxymethylcellulose (CMC) from the Netherlands. This administrative review covers imports of subject merchandise produced and exported by Akzo Nobel Functional Chemicals B.V. during the period of review (POR) of July 1, 2009, through June 30, 2010.

We preliminarily determine that sales of subject merchandise by Akzo Nobel Functional Chemicals B.V. were made at less than normal value during the period of review. If these preliminary results are adopted in our final results of administrative review, we will issue appropriate assessment instructions to U.S. Customs and Border Protection (CBP). Interested parties are invited to comment on these preliminary results. Parties who submit argument in this review are requested to submit with the argument: (1) A statement of the issues; (2) a brief summary of the argument; and (3) a table of authorities.

DATES: *Effective Date:* June 22, 2011.

FOR FURTHER INFORMATION CONTACT: Dena Crossland or David Cordell, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–3362 or (202) 482–0408, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 11, 2005, the Department published the antidumping duty order on CMC from the Netherlands. *See Notice of Antidumping Duty Orders: Purified Carboxymethylcellulose from Finland, Mexico, the Netherlands, and Sweden,* 70 FR 39734 (July 11, 2005) (*CMC Order*). On July 1, 2010, the Department published an opportunity to request an administrative review of this order for the period July 1, 2009, through June 30, 2010. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 75 FR 38074 (July 1, 2010).

Pursuant to 19 CFR 351.213(b)(1), Aqualon Company (Aqualon), petitioner in this proceeding, filed a July 26, 2010, request that the Department conduct an administrative review of the sales of subject merchandise from Akzo Nobel Functional Chemicals B.V. (ANFC) and CP Kelco B.V. (CP Kelco) during the POR. On July 27, 2010, CP Kelco requested a review of its sales of subject merchandise and, on July 30, 2010, ANFC requested a review of its sales of subject merchandise made during the POR. On August 18, 2010, CP Kelco withdrew its request for an administrative review of its sales of subject merchandise during the POR. Additionally, on August 18, 2010, Aqualon withdrew its request for an administrative review with respect to CP Kelco.

On August 31, 2010, the Department published a notice of initiation of this administrative review, covering exports, sales, and/or entries of purified CMC from ANFC in the **Federal Register**. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Deferral of Initiation of Administrative Review,* 75 FR 53274 (August 31, 2010).

The Department issued its antidumping duty questionnaire to ANFC on September 28, 2010. ANFC responded to the questionnaire on November 2, 2010 (section A questionnaire response (AQR), and on November 17, 2010 (sections B and C questionnaire responses (BQR and CQR)).

On December 7, 2010, Aqualon filed a request for a sales-below-cost investigation of ANFC, in which it alleged that ANFC had made home market sales of purified CMC at prices below the cost of production (COP) during the POR. After reviewing the allegation, the Department initiated a cost investigation of ANFC on January 20, 2011, and requested that the company respond to section D of the questionnaire. ANFC filed its section D questionnaire response (DQR) on February 17, 2011.

ANFC responded to supplemental questionnaires concerning sections A through C of the Department's questionnaire on March 7, 2011, April 25, 2011, and May 19, 2011. ANFC responded to supplemental questionnaires concerning section D of the Department's questionnaire on April 18, 2011, May 9, 2011, May 17, 2011, and May 19, 2011.

On April 1, 2011, the Department extended the deadline for the preliminary results of review from April 2, 2011, until June 16, 2011. *See Purified Carboxymethylcellulose From the Netherlands; Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review,* 76 FR 18156 (April 1, 2011).

Period of Review

The POR is July 1, 2009, through June 30, 2010.

Scope of the Order

The merchandise covered by this order is all purified CMC, sometimes also referred to as purified sodium CMC, polyanionic cellulose, or cellulose gum, which is a white to off-white, non-toxic, odorless, biodegradable powder, comprising sodium CMC that has been refined and purified to a minimum assay of 90 percent. Purified CMC does not include unpurified or crude CMC, CMC Fluidized Polymer Suspensions, and CMC that is cross-linked through heat treatment. Purified CMC is CMC that has undergone one or more purification operations, which, at a minimum, reduce the remaining salt and other by-product portion of the product to less than ten percent. The merchandise subject to this order is currently classified in the Harmonized Tariff Schedule of the United States at subheading 3912.31.00. This tariff classification is provided for convenience and Customs purposes; however, the written description of the scope of this order is dispositive.

Date of Sale

For its home market sales, ANFC reported its date of sale to be the invoice date, which coincided with the loading and shipment date of the merchandise. It stated that, until the time that the merchandise is loaded, changes can occur in the material terms of sale. *See* ANFC's BQR at B–11. Similarly, for its warehouse sales in the United States (constructed export price (CEP) Channel 2 sales), ANFC reported the date of sale to be the invoice date, which is the date that merchandise is loaded for shipment from the warehouse and, because material changes can take place prior to loading, the invoice date is the date on which the terms of sale are set. *See* ANFC's CQR at C–11 and C–12. However, for sales in which the product was shipped directly from the Netherlands to the United States (CEP Channel 1 sales), ANFC reported the date of shipment as the date of sale as this date preceded the invoice date. *See* ANFC's CQR at C–12. In its description of the sales process for these sales, ANFC stated that material terms, such as the quantity or price of the merchandise, could change prior to invoicing from ANFC's U.S. affiliate to the U.S. customer. *See* ANFC's AQR at A–28, A–29, and A–31; *see also* ANFC's supplemental questionnaire response, dated March 7, 2011, at 7 and Tabs 2–3. We noted that the unaffiliated customer is not invoiced by AN–US until the customer receives the merchandise from the Netherlands. *See* ANFC's AQR at A–28 and A–29.

Normally, the Department considers invoice date as the date of sale in accordance with 19 CFR 351.401(i). However, it is the Department's practice to use shipment date as the date of sale when shipment date precedes invoice date. *See Certain Cold-Rolled and Corrosion-Resistant Carbon Steel Flat Products From Korea: Final Results of Antidumping Duty Administrative Reviews,* 63 FR 13170, 13172–73 (March 18, 1998); *see also Stainless Steel Sheet and Strip in Coils from the Republic of Korea; Final Results and Rescission of Antidumping Duty Administrative Review in Part,* 72 FR 4486 (January 31, 2007), and the accompanying Issues and Decision Memorandum at Comments 4 and 5.

Although ANFC asserts that material terms of sale for its direct sales to the United States may change between the time of shipment of the goods from the Netherlands and the issuance of an invoice by AN–US, we find that the quantity and price for these sales are established at the time the merchandise was shipped from the Netherlands. *See*

ANFC's CQR at C–11 and C–12. Therefore, we preliminarily determine that invoice date is the appropriate date of sale for ANFC's home market and U.S. sales, except for ANFC's U.S. sales in which shipment occurred prior to invoice date. Consistent with past segments of this preceding and the Department's practice, we used the shipment date as the date of sale for those sales.

Fair Value Comparisons

To determine whether sales of purified CMC from the Netherlands to the United States were made at less than fair value, we compared the CEP of each sale to the normal value, as described in the ''Constructed Export Price'' and ''Normal Value'' sections of this notice below. In accordance with section 777A(d)(2) of the Tariff Act of 1930, as amended (the Act), we compared the CEPs of individual U.S. transactions to monthly weighted-average normal values.

Product Comparisons

In accordance with section 771(16) of the Act, we considered all purified CMC that fit the description in the ''Scope of the Order'' section above and that was produced and sold by ANFC in the Netherlands during the POR to be foreign like product for the purpose of determining appropriate product comparisons to purified CMC sold by the respondent in the United States. For our discussion of home market viability, *see* the ''Normal Value'' section of this notice below. We compared the U.S. sales with the sales of the foreign like product in the comparison market.

Specifically, in making our comparisons, we used the following methodology. If sales of an identical comparison-market model were reported, we compared the CEPs of the U.S. sales to the weighted-average, comparison-market prices of all sales that passed the COP test of the identical product during the relevant or contemporary month. *See* sections 771(16) and (35) of the Act; *see also* section 773(b)(1) of the Act. If there were no contemporaneous sales of an identical model, we identified sales of the most similar comparison-market model. See section 771(16) of the Act. To determine the most similar model, we matched the physical characteristics of the foreign like product, as reported by ANFC, to the characteristics of the subject merchandise in the following order of importance: (1) Grade, (2) viscosity, (3) degree of substitution, (4) particle size, and (5) solution characteristics. Where there were no sales of identical or similar foreign like product in the ordinary course of trade with which to compare to a U.S. sale, we made product comparisons using constructed value.

Constructed Export Price

In accordance with section 772 of the Act, we calculate either an export price or a CEP, depending on the nature of each sale. Section 772(b) of the Act defines CEP as the price at which the subject merchandise is first sold (or agreed to be sold) in the United States before or after the date of importation by or for the account of the producer or exporter of such merchandise, or by a seller affiliated with the producer or exporter, to a purchaser not affiliated with the producer or exporter.

ANFC classified all of its sales to the United States as sales made through its U.S. affiliate, AN–US, to end-users and distributors (*i.e.,* CEP sales). For purposes of these preliminary results, we have accepted this classification.

We calculated CEP based on prices charged to the first unaffiliated U.S. customer. As discussed in the ''Date of Sale'' section above, we used invoice date as the date of sale for CEP sales, except in instances where the date of shipment preceded the invoice date. We based CEP on the gross unit price to the first unaffiliated U.S. customer, making adjustments where necessary for billing adjustments. *See* 19 CFR 351.401(c). Where applicable, and pursuant to sections 772(c)(2)(A) and (d)(1) of the Act, the Department made deductions for movement expenses, including deductions for domestic foreign inland freight and warehousing expenses, domestic inland insurance, domestic brokerage and handling expenses, international freight, marine insurance, U.S. inland insurance, brokerage and handling expenses incurred in the United States, U.S. warehousing expenses, U.S. inland freight, and U.S. customs duties.

In accordance with section 772(d)(1) of the Act, we also deducted, where applicable, U.S. direct selling expenses (*i.e.,* credit expenses) and indirect selling expenses and inventory carrying costs incurred in the Netherlands and the United States and associated with economic activities in the United States.

We deducted an amount for CEP profit in accordance with section 772(d)(3) of the Act.

Normal Value

A. Home Market Viability and Comparison Market Selection

In order to determine whether there is a sufficient volume of sales in the home market to serve as a viable basis for calculating normal value (*i.e.,* whether the aggregate volume of home market sales of the foreign like product is equal to or greater than five percent of the aggregate volume of U.S. sales), we compared ANFC's volume of home market sales of the foreign like product to the volume of U.S. sales of the subject merchandise, in accordance with section 773(a)(1)(C) of the Act.

A review of the record shows that ANFC's home market sales were viable, for purposes of comparing them to U.S. sales. *See* ANFC's AQR at A–3 and Exhibit 1. Thus, we based normal value on ANFC's home market sales made in the usual commercial quantities and in the ordinary course of trade.

B. Cost of Production Analysis

Based on Aqualon's cost allegation, the Department had reasonable grounds to believe or suspect that ANFC made below-cost sales of the foreign like product. *See* section 773(b)(2)(A)(i) of the Act. Therefore, the Department initiated a cost investigation of ANFC on January 20, 2011, and requested that ANFC file a response to section D of the antidumping duty questionnaire on that date.

C. Calculation of Cost of Production

We have preliminarily relied upon the COP information provided by ANFC in its section D submission, except as noted below. In accordance with section 773(b)(3) of the Act, we calculated the weighted-average COP for each foreign like product based on the sum of ANFC's material and fabrication costs for the product, plus amounts for selling, general, and administrative (SG&A) expenses, as well as packing costs. Based on the review of record evidence, ANFC did not appear to experience significant changes in its cost of manufacturing during the POR. Therefore, we followed our normal methodology of calculating an annual weighted-average cost. We relied on the COP data provided in ANFC's May 17, 2011, submission, except for the following instances:

During the POR, ANFC stated that it purchased two major inputs, mono-chloroacetic acid (MCA) and caustic soda, from a home market affiliated company.[1] Section 773(f)(3) of the Act (the major input rule) states:

[1] *See* ANFC's DQR at D–7. For further discussion of these inputs, Memorandum from Christopher Zimpo, Accountant, to Neal M. Halper, Director, Office of Accounting, regarding ''Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Results—Akzo Nobel Functional Chemicals B.V.,'' dated June 16, 2011 (Calculation Memo), at pages 1–2 and Attachment 1.

If, in the case of a transaction between affiliated persons involving the production by one of such persons of a major input to the merchandise, the administering authority has reasonable grounds to believe or suspect that an amount represented as the value of such input is less than the cost of production of such input, then the administering authority may determine the value of the major input on the basis of the information available regarding such cost of production, if such cost is greater than the amount that would be determined for such input under paragraph (2).

Paragraph 2 of section 773(f) of the Act (transactions disregarded) states:

A transaction directly or indirectly between affiliated persons may be disregarded if, in the case of any element of value required to be considered, the amount representing that element does not fairly reflect the amount usually reflected in sales of merchandise under consideration in the market under consideration. If a transaction is disregarded under the preceding sentence and no other transactions are available for consideration, the determination of the amount shall be based on the information available as to what the amount would have been if the transaction had occurred between persons who are not affiliated.

In accordance with the major input rule, and as stated in *Stainless Steel Sheet and Strip in Coils From Mexico; Preliminary Results of Antidumping Duty Administrative Review,* 73 FR 45708, 45714 (August 6, 2008), unchanged in *Stainless Steel Sheet and Strip in Coils from Mexico; Final Results of Antidumping Duty Administrative Review,* 74 FR 6365 (February 9, 2009), it is the Department's normal practice to use all three elements of the major input rule (*i.e.,* transfer price, COP, and market price) where available. In accordance with section 773(f)(3) of the Act (the major input rule), we evaluated transactions between ANFC and its affiliate using the transfer price, COP and market price of MCA and caustic soda. For the preliminary results, we adjusted ANFC's reported costs to reflect the highest of these three values for ANFC's affiliated purchases of MCA and caustic soda. For further discussion of these adjustments, *see* Calculation Memo.

We adjusted ANFC's and its affiliate's general and administrative (G&A) expense calculation for certain non-operating income and expense items in accordance with the Department's practice of including in G&A certain non-operating amounts which relate to the general operations of the company as a whole. *See Magnesium Metal from the Russian Federation: Notice of Final Determination of Sales at Less Than Fair Value,* 70 FR 9041 (February 24, 2005), and accompanying Issues and Decision Memorandum at Comment 10. We did not allow certain non-operating income to offset the reported G&A expenses because ANFC did not support why they were appropriate reductions to the reported G&A expenses. We excluded net foreign exchange gains and losses from ANFC's reported G&A expense calculation because these are accounted for elsewhere in the COP calculation, specifically in the net financial expense rate. For further discussion of these adjustments, *see* Calculation Memo.

D. Test of Comparison Market Prices

As required under section 773(b) of the Act, we compared ANFC's weighted-average COP figures to its comparison-market sales prices (net of certain discounts, any applicable movement expenses, direct and indirect selling expenses, and packing) of the foreign like product in order to determine whether sales in the comparison market had been made at prices below COP. In determining whether to disregard such sales, we examined, in accordance with sections 773(b)(1)(A) and (B) of the Act, whether such sales were made within an extended period of time in substantial quantities and whether the sales were made at prices which would not permit the recovery of all costs within a reasonable period of time.

E. Results of Cost Test

Pursuant to section 773(b)(2)(C) of the Act, where less than 20 percent of the sales of a given product were at prices less than the COP, we did not disregard any of the below-cost sales of that product because they were not made in substantial quantities. However, where 20 percent or more of the respondent's comparison-market sales of a model were made at prices below the COP, we disregarded these sales because they were made: (1) In substantial quantities within the POR (*i.e.,* within an extended period of time), in accordance with sections 773(b)(2)(B) and (C) of the Act; and (2) at prices which would not permit recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act. We used the remaining comparison-market sales, if such sales existed and were made in the ordinary course of trade, as the basis for determining normal value, in accordance with section 773(b)(1) of the Act.

In the current review, we found sales by ANFC made below the COP for 20 percent or more of certain models and, therefore, we disregarded these below-cost sales from our margin calculations. *See* ANFC's Preliminary Analysis Memorandum at page 11.

F. Price-to-Price Comparisons

We calculated normal value based on prices to unaffiliated customers in the comparison market. In this market, we used invoice date as the date of sale except where shipment preceded invoice date, in which cases we used shipment date as date of sale. *See* 19 CFR 351.401(i). We decreased price, as appropriate, for certain discounts. We made deductions, where appropriate, for foreign inland freight and international freight pursuant to section 773(a)(6)(B) of the Act. In addition, when comparing sales of similar merchandise to U.S. sales, we made adjustments to normal value for differences in cost attributable to differences in physical characteristics of the merchandise, pursuant to section 773(a)(6)(C)(ii) of the Act and 19 CFR 351.411, as well as for differences in circumstances of sale, as appropriate (*i.e.,* credit), in accordance with section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410. We also made an adjustment, where appropriate, for a CEP offset, in accordance with section 773(a)(7)(B) of the Act. See the ''Level of Trade'' section below. Finally, we deducted comparison-market packing costs and added U.S. packing costs to normal value, in accordance with sections 773(a)(6)(A) and (B) of the Act.

G. Price-to-Constructed-Value Comparisons

Section 773(a)(4) of the Act provides that, if we are unable to find a contemporaneous comparison-market match of identical or similar merchandise for a U.S. sale, then we base normal value on constructed value. Section 773(e) of the Act provides that constructed value shall be based on the sum of the cost of materials and fabrication employed in producing the merchandise, SG&A expenses, profit, and expenses associated with packing the merchandise for shipment to the United States. We calculated the cost of materials and fabrication based on the methodology described above in the ''Calculation of Cost of Production'' section. In accordance with section 773(e)(2)(A) of the Act, we based SG&A expenses (as adjusted above) and profit on the amounts incurred and realized by ANFC in connection with the production and sale of the foreign like product, in the ordinary course of trade, for consumption in the foreign country. *See* 19 CFR 351.405(b)(1).

Level of Trade

In accordance with section 773(a)(1)(B)(i) of the Act, to the extent practicable, we determine normal value based on sales in the comparison market at the same level of trade as the export price or CEP transaction. The level of trade in the comparison market is the level of trade of the starting-price sales in the comparison market or, when normal value is based on constructed value, the level of trade of the sales from which we derive SG&A expenses and profit. *See* 19 CFR 351.412(c). For CEP, the level of trade is that of the constructed sale from the exporter to the importer. *Id.*

To determine whether comparison market sales are at a different level of trade from U.S. sales, we examine stages in the marketing process and selling functions along the chain of distribution between the producer and the unaffiliated customer. If the comparison market sales are at different levels of trade, and the difference affects price comparability, as manifested in a pattern of consistent price differences between the sales on which normal value is based and comparison market sales at the level of trade of the export transaction, the Department makes a level-of-trade adjustment in accordance with section 773(a)(7)(A) of the Act. For CEP sales, we examine stages in the marketing process and selling functions along the chain of distribution between the producer and the customer. We analyze whether different selling activities are performed, and whether any price differences (other than those for which other allowances are made under the Act) are shown to be wholly or partly due to a difference in level of trade between the CEP and normal value. *See* section 773(a)(7)(A) of the Act.

Under section 773(a)(7)(A) of the Act, we make an upward or downward adjustment to normal value for level of trade if the difference in level of trade involves the performance of different selling activities and is demonstrated to affect price comparability, based on a pattern of consistent price differences between sales at different levels of trade in the country in which normal value is determined. Finally, if the normal-value level of trade is at a more advanced stage of distribution than the level of trade of the CEP, but the data available do not provide an appropriate basis to determine a level-of-trade adjustment, we reduce normal value by the amount of indirect selling expenses incurred in the comparison market on sales of the foreign like product, but by no more than the amount of the indirect selling expenses incurred for CEP sales. *See* section 773(a)(7)(B) of the Act (the CEP-offset provision).

In analyzing differences in selling functions, we determine whether the levels of trade identified by the respondent are meaningful. *See Antidumping Duties: Countervailing Duties,* 62 FR 27296, 27371 (May 19, 1997). If the claimed levels of trade are the same, we expect that the functions and activities of the seller should be similar. Conversely, if a party claims that levels of trade are different for different groups of sales, the functions and activities of the seller should be dissimilar. *See Porcelain-on-Steel Cookware from Mexico: Final Results of Antidumping Duty Administrative Review,* 65 FR 30068 (May 10, 2000), and accompanying Issues and Decision Memorandum at Comment 6.

In the present review, ANFC claimed that a CEP offset was required because the CEP level of trade was less advanced than levels of trade in the comparison market. *See* ANFC's CQR at C–54 and C–55. In order to determine whether the comparison market sales were at different stages in the marketing process than the U.S. sales, we reviewed the distribution system in each market (*i.e.,* the ''chain of distribution''),[2] including selling functions, class of customer (customer category), and the level of selling functions for each type of sale.

ANFC reported one level of trade in the home market, the Netherlands, with one channel of distribution to two classes of customers: (1) Direct sales from the warehouse located near the ANFC manufacturing plant to end users, and (2) direct sales from the warehouse located near the ANFC manufacturing plant to distributors. *See* ANFC's AQR at A–17; *see also* ANFC's BQR at B–10. Based on our review of evidence on the record, we find that the home market sales to both customer categories through the one channel of distribution were substantially similar with respect to selling functions and stages of marketing. ANFC performed the same selling functions for sales in a single home market channel of distribution, including sales forecasting, strategic planning, advertising, distributor training, packing, warehousing, inventory management, order processing, direct sales crew, market research, providing guarantees, after sales services, freight and delivery, and invoicing. *See* ANFC's AQR at A–19 through A–23 and Tab 9. Each of these selling functions was identical in the intensity of their provision or only differed minimally, the exception being that ANFC provided sales/marketing support and technical assistance to a different degree of involvement to different customer types. *See* ANFC's AQR at Tab 9. *See also* Preliminary Analysis Memorandum. Thus, after considering all of the above, we preliminarily find that ANFC had only one LOT for its home market sales.

ANFC reported one CEP LOT, with two separate channels of distribution in the United States. CEP Channel 1 sales were made to order for two classes of customers, *i.e.,* end users and distributors. *See* ANFC's AQR at A–17. The U.S. customer orders merchandise from ANFC's U.S. affiliate, AN–US, and the merchandise is shipped directly to the U.S. customer from ANFC. *Id.* Further, the customer is invoiced by AN–US, and the title passed directly from the AN–US to the unaffiliated customer in the United States. CEP Channel 2 sales were also made to two classes of customers, *i.e.,* end users and distributors, from inventory. *Id.* Specifically, the U.S. customer orders merchandise from AN–US, which is shipped out of a stock of materials maintained at AN–US's unaffiliated warehouses. *Id.* Upon examining ANFC's questionnaire responses, we preliminarily find that it has two channels of distribution for its CEP sales in the United States. *See* ANFC's AQR at A–16 through A–17, A–27 through A–29, and Tab 8; and CQR at C–10.

For CEP sales, we consider only the selling activities reflected in the price after the deduction of expenses and CEP profit under section 772(d) of the Act. *See Micron Tech. Inc.* v. *United States,* 243 F.3d 1301, 1314–15 (Fed. Cir. 2001). We reviewed the selling functions and services performed by ANFC on CEP sales as described in its questionnaire and supplemental questionnaire responses, after these deductions. We found that selling functions performed by ANFC to its U.S. affiliate in support of the CEP sales were almost identical regardless of class of customers or channel of trade. ANFC reported that it provided services to both CEP channels including strategic planning, packing, warehousing, inventory management, order processing, and logistics for freight and delivery. *See* ANFC's AQR at Tab 9. ANFC reported that the only services it provided for the CEP Channel 1 sales to a different degree of performance comparatively to the

[2] The marketing process in the United States and comparison market begins with the producer and extends to the sale to the final user or customer. The chain of distribution involved in the two markets may have many or few links, and respondent's sales occur somewhere along this chain. In performing this evaluation, we considered respondent's narrative responses to properly determine where in the chain of distribution the sale occurs.

degree of performance provided for Channel 2 sales were logistics for freight and delivery, warehousing, and inventory management. *Id.* Therefore, we found that selling functions performed by ANFC for both channels are at the same level.

Next, we compared the stages in the marketing process and selling functions along the chain of distribution for home market and CEP sales. ANFC's home market and CEP sales were both made to end users and distributors. We found that ANFC performs an additional layer of selling functions at a greater degree of involvement in the home market than it provided on CEP Channel 1 and Channel 2 sales (*e.g.,* sales forecasting, strategic planning, advertising, distributor training, market research, technical assistance, sales and marketing support, after sales service, and invoicing). *See* ANFC's AQR at A–19 through A–23 and Tab 9. Because these additional selling functions are significant, we find that ANFC's CEP sales are at a different level of trade than its home market sales.

According to section 773(a)(7)(B) of the Act, a CEP offset is appropriate when the level of trade in the home market is at a more advanced stage than the level of trade of the CEP sales and there is no basis for determining whether the difference in levels of trade between normal value and CEP affects price comparability. ANFC reported that it provided minimal selling functions and services for the CEP level of trade and that, therefore, the home market level of trade is more advanced than the CEP level of trade. Based on our analysis of the channels of distribution and selling functions performed by ANFC for sales in the home market and CEP sales in the U.S. market (*i.e.,* sales support and activities provided by ANFC for sales to its U.S. affiliate), we preliminarily find that the home market level of trade is at a more advanced stage when compared to CEP sales because ANFC provides many selling functions in the home market at a different level of service (*i.e.,* sales forecasting, advertising, distributor training, market research, sales and marketing support, etc.) as compared to selling functions performed for its CEP sales (*i.e.,* ANFC reported that the only services it provided for the CEP sales were logistics for freight and delivery, packing, warehousing, inventory management, order processing, providing guarantees, and limited strategic planning and technical assistance). *See* ANFC's AQR at Tab 9. Thus, we find that ANFC's home market sales are at a more advanced level of trade than its CEP sales. As there was only one level of trade in the home market, there were no data available to determine the existence of a pattern of price differences, and we do not have any other information that provides an appropriate basis for determining a level-of-trade adjustment; therefore, we applied a CEP offset to normal value for CEP comparisons.

To calculate a CEP offset for ANFC, we deducted the comparison market indirect selling expenses from normal value for sales that were compared to U.S. CEP sales. We limited the deduction by the amount of the indirect selling expenses deducted in calculating the CEP under section 772(d)(1)(D) of the Act. See section 773(a)(7)(B) of the Act.

Currency Conversion

We made foreign-currency conversions into U.S. dollars in accordance with section 773A(a) of the Act and 19 CFR 351.415 based on exchange rates in effect on the dates of the U.S. sales, as certified by the Federal Reserve Bank. *See* Import Administration Web site at: *http://ia.ita.doc.gov/exchange/index.html.*

Preliminary Results of Review

We preliminarily determine that, for the period July 1, 2009, through June 30, 2010, the following dumping margin exists:

Manufacturer/exporter	Weighted-average margin (percent)
Akzo Nobel Functional Chemicals	B.V. 3.24

Disclosure and Public Comment

Pursuant to 19 CFR 351.224(b), the Department will disclose to parties to the proceeding any calculations performed in connection with these preliminary results within five days after the date of publication of this notice. Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit written comments in response to these preliminary results. Interested parties may submit case briefs to the Department no later than 30 days after the publication of these preliminary results. *See* 19 CFR 351.309(c)(1)(ii). Rebuttal briefs, the content of which is limited to the issues raised in the case briefs, must be filed within five days from the deadline date for the submission of case briefs. *See* 19 CFR 351.309(d)(1) and (2).

Parties who submit arguments in this proceeding are requested to submit with the argument: (1) A statement of the issues; (2) a brief summary of the argument; and (3) a table of authorities. *See* 19 CFR 351.309(c)(2). Case and rebuttal briefs must be served on interested parties in accordance with 19 CFR 351.303(f). Executive summaries should be limited to five pages total, including footnotes. Furthermore, we request that parties, when submitting briefs and rebuttal briefs, provide the Department with a copy of the public versions of the briefs on diskette.

Within 30 days of the date of publication of this notice, interested parties may request a public hearing on arguments raised in the case and rebuttal briefs, pursuant to 19 CFR 351.310(c). Unless the Department specifies otherwise, the hearing, if requested, will be held two days after the date for submission of rebuttal briefs. *See* 19 CFR 351.310(d)(1). Parties will be notified of the time and location of the hearing.

The Department will publish the final results of the administrative review, including the results of its analysis of issues addressed in any case or rebuttal brief, no later than 120 days after publication of the preliminary results, unless extended. *See* section 751(a)(3)(A) of the Act; 19 CFR 351.213(h).

Assessment Rates

The Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries. In accordance with 19 CFR 351.212(b)(1), we have calculated, whenever possible, an exporter/importer (or customer)-specific assessment rate or value for merchandise subject to this review as described below.

For CEP sales, we divide the total dumping margins for the reviewed sales by the total entered value of those reviewed sales for each importer. We will direct CBP to assess the resulting percentage margin against the entered customs values for the subject merchandise on each of that importer's POR entries. *See* 19 CFR 351.212(b).

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 companies in these preliminary results of review for which the reviewed companies did not know their 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 liquidation instructions to CBP 15 days after publication of the final results of this review. We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any importer-specific assessment rate calculated in the final results of this review is above *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 assessment rate is *de minimis.* 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 duties, where applicable. *See* section 751(a)(2)(C) of the Act.

Cash Deposit Requirements

The following cash-deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date 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 the company listed above will be that 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 listed above, 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 or in the 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 the all-others rate of 14.57 percent, which is the all-others rate established in the investigation. *See CMC Order,* 70 FR at 39735. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a 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 Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: June 16, 2011.

Christian Marsh,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–15648 Filed 6–21–11; 8:45 am]

BILLING CODE 3510–DS–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Renew Collection, Exemptions From Speculative Limits

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (CFTC) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on exemptions from speculative limits.

DATES: Comments must be submitted on or before August 22, 2011.

ADDRESSES: Comments may be mailed to Gary Martinaitis, Division of Market Oversight, U.S. Commodity Futures Trading Commission, 1155 21st Street, NW., Washington, DC 20581.

FOR FURTHER INFORMATION CONTACT: Gary Martinaitis, (202) 418–5209; FAX: (202) 418–5527; e-mail: *gmartinaitis@cftc.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of 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.

Exemptions From Speculative Limits, OMB Control Number 3038–0013—Extension

Section 4a(a) of the Commodity Exchange Act (Act) allows the Commission to set speculative limits in any commodity for future delivery in order to prevent excessive speculation. Certain sections of the Act and/or the Commission's Regulations allow exemptions from the speculative limits for persons using the market for hedging and, under certain circumstances, for commodity pool operators and similar traders. This information collection contains the recordkeeping and reporting requirements needed to ensure regulatory compliance with Commission rules relating to this issue.

The Commission estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

Regulations (17 CFR)	Estimated number of respondents	Reports annually by each respondent	Total annual responses	Estimated number of hours per response	Annual burden
Rule 1.47 and 1.48	7	2	14	3	42
Part 150	2	1	2	3	6

There are no capital costs or operating and maintenance costs associated with this collection.

Dated: June 16, 2011.

David Stawick,

Secretary of the Commission.

[FR Doc. 2011–15609 Filed 6–21–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF EDUCATION

Notice of Submission for OMB Review

AGENCY: Department of Education.

ACTION: Comment Request.

SUMMARY: The Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

DATES: Interested persons are invited to submit comments on or before July 22, 2011.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, *Attention:* Education Desk Officer, Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503, be faxed to (202) 395–5806 or e-mailed to *oira_submission@omb.eop.gov* with a cc: to *ICDocketMgr@ed.gov.* Please note that written comments received in response to this notice will be considered public records.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The OMB is particularly interested in comments which: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: June 16, 2011.

James Hyler,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

Office of Planning, Evaluation and Policy Development

Type of Review: New.

Title of Collection: Evaluation of the Education for Homeless Children and Youth Program.

OMB Control Number: 1875–NEW.

Agency Form Number(s): N/A.

Frequency of Responses: Once.

Affected Public: State, Local, or Tribal Government, State Educational Agencies or Local Educational Agencies.

Total Estimated Number of Annual Responses: 256.

Total Estimated Annual Burden Hours: 151.

Abstract: The evaluation will survey state coordinators and district liaisons for Education for Homeless Children and Youth (EHCY) Program. The evaluation addresses research questions in the following areas of program implementation: (1) The collection and use of data on homeless children and youth; (2) the expenditure of EHCY Program funds; (3) the policies and services provided by local educational agencies to remove barriers that prevent homeless children and youth from accessing a free, appropriate public education; and (4) the coordination of such efforts at the local level.

Copies of the information collection submission for OMB review may be accessed from the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAMain* or from the Department's Web site at *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 4559. When you access the information collection, click on ''Download Attachments '' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to the Internet address *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2011–15597 Filed 6–21–11; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP11–490–000]

Columbia Gas Transmission, LLC; Notice of Application

Take notice that on May 20, 2011, Columbia Gas Transmission, LLC (Columbia), filed an application pursuant to section 7(c) of the Natural Gas Act and part 157 of the Commission's Regulations, for a certificate of public convenience and necessity to construct and operate a 2.47-mile of 20-inch pipeline to transport natural gas for Virginia Power Services Energy Corp., Inc. (VPSEC) in Warren County, Virginia. Additionally, Columbia will construct a new measurement and regulation station, and other appurtenant facilities located in Montgomery County, Maryland, Loudon County, Virginia and Hardy County, West Virginia. The filing may also be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at

FERCOnlineSupport@gerc.gov or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The purpose of the project is to provide firm capacity for the transportation of natural gas to be used in the operation of a new gas-fired electric generation facility being constructed by Virginia Electric and Power Company d/b/a Dominion Virginia Power (VEPCO) in Warren County, Virginia (VEPCO-Warren Project). The VEPCO-Warren Project will enable Columbia to provide up to 224 MDth/day and 246 MDth/day of firm transportation service to VPSEC from April through September and October through March, respectively. The applicable rates for service during the term of the service agreements will be the maximum rates set forth in Columbia's tariff for service under the applicable rate schedules. Columbia also requests a rolled-in-rate treatment for the VEPCO-Warren Project. The estimated cost of the VEPCO-Warren County Project is $34,300,000. VEPCO expects to complete the construction and place the electric generation facility in service during 2014.

Any questions regarding this application should be directed to Fredric J. George, Lead Counsel, Columbia Gas Transmission, LLC, P.O. Box 1273, Charleston, West Virginia 25325–1273; telephone 304–357–2359, fax 304–357–3206.

Any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the below listed comment date, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit original and 7 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

Motions to intervene, protests and comments may be filed electronically via the Internet in lieu of paper, see, 18 CFR 385.2001 (a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Comment Date: June 27, 2011.

Dated: June 6, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–15546 Filed 6–21–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 349–150]

Alabama Power Company (Alabama Power); Notice of Application Tendered for Filing With the Commission and Establishing Procedural Schedule for Licensing and Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 349–150.

c. *Date Filed:* June 8, 2011.

d. *Applicant:* Alabama Power Company (Alabama Power).

e. *Name of Project:* Martin Dam Hydroelectric Project.

f. *Location:* The existing Martin Dam Project is located on the Tallapoosa River in northeast Alabama, in Tallapoosa, Coosa, and Elmore Counties, Alabama, near the cities of Alexander City and Dadeville, Alabama. The project would occupy 1.36 acres of Federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Theodore J. McCullough, Senior Vice President and Senior Production Officer, Alabama Power Company, 600 North 18th Street, P.O. Box 2641, Birmingham, AL 35291, telephone (205) 257–8180; James F. Crew, Manager, Hydro Services, Alabama Power Company, 600 North 18th Street, P.O. Box 2641, Birmingham, AL 35291, telephone (205) 257–4265.

i. *FERC Contact:* Jennifer Adams, (202) 502–8087 or *jennifer.adams@ferc.gov.*

j. This application is not ready for environmental analysis at this time.

k. *The Project Description:* Martin Dam is located at river mile 420.0 on the Tallapoosa River near the cities of Alexander City and Dadeville, Alabama. Martin Dam impounds about 31 miles of the Tallapoosa River, forming Martin Reservoir (or Lake Martin), a 40,000-acre reservoir with (a) 700 miles of shoreline, (b) a gross storage capacity of 1,622,000 acre-feet, and (c) active storage of 1,381,077 acre-feet at a 45.5-foot drawdown.

The existing Martin Dam Project consists of: (1) A concrete gravity dam and an earth dike section, totaling about 2,000 feet in length with a maximum height of 168 feet, and includes (a) A 720-foot-long gated spillway section with 20 vertical lift spillway gates, each measuring 30 feet wide by 16 feet high; (b) a 250-foot-long concrete gravity intake structure, (c) a 255-foot-long concrete gravity non-overflow section, and (d) an approximately 1,000-foot-long earth embankment; (2) a reservoir with a surface area of 40,000 acres at the normal full pool elevation of 491 feet mean sea level (msl); (3) headworks containing four steel penstocks and 12 intake gates, each fitted with trash racks; (4) a brick and concrete, steel-frame powerhouse, 307 feet long, 58 feet wide, and 99 feet high; (5) four vertical Francis turbines that power four generating units with a total installed capacity of 182.5 MW; (6) two 450-foot-long transmission lines; and (7) appurtenant facilities. The project generates about 33,000,000 megawatt-hours (MWh) annually.

The Martin Dam Project operates as a peaking project using a multipurpose storage reservoir (Lake Martin), in which the water levels fluctuate seasonally. Under its normal peaking operations, the project operates between elevations 481 and 491 feet msl. Flows from the dam vary from leakage during periods of non-generation to 17,900 cubic feet per second (cfs) during generation. The Martin Dam Project typically generates Monday through Friday for eight hours per day. Releases from Martin Dam are made directly into Alabama Power's Yates and Thurlow Hydroelectric Project (FERC Project No. 2407). The Thurlow Dam is required to release a minimum flow of 1,200 cfs. Releases from Martin Dam are often necessary to maintain the 1,200-cfs minimum flow requirement.

Alabama Power uses three guide curves for the Martin Dam Project: (1) A flood control guide; (2) an operating guide; and (3) a drought contingency curve. The flood control guide maximizes lake elevations for flood control purposes. The operating guide limits fluctuations in Lake Martin to water levels that stakeholders deemed acceptable during the previous relicensing process for the Martin Dam Project. The area between the flood control guide and operating guide represents the range that Alabama Power operates the project under normal inflow conditions.

l. *Locations of the Application:* A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. *Procedural Schedule:*

The application will be processed according to the following preliminary Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Notice of Acceptance/Notice of Ready for Environmental Analysis	August 7, 2011
Filing of recommendations, preliminary terms and conditions, and fishway prescriptions	October 6, 2011.
Commission issues Draft EIS	April 3, 2012.
Comments on Draft EIS	June 2, 2012.
Modified Terms and Conditions	August 1, 2012.
Commission Issues Final EIS	October 30, 2012.

o. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the Notice of Ready for Environmental Analysis.

Dated: June 15, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–15526 Filed 6–21–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER01–468–012; ER00–3621–013; ER04–318–009; ER05–36–009; ER05–37–009; ER05–34–009; ER05–35–009; ER04–249–009; ER99–1695–018; ER02–23–016; ER07–1306–008; ER97–30–010; ER96–2869–017; ER08–1323–004; ER97–3561–009.

Applicants: Dominion Energy Marketing, Inc., Dominion Nuclear Connecticut, Inc., Dominion Energy Kewaunee, Inc., Dominion Energy Brayton Point, LLC, Dominion Energy Manchester Street, Inc., Dominion Energy New England, Inc., Dominion Energy Salem Harbor, LLC, Dominion Retail, Inc., Elwood Energy, LLC, Fairless Energy, LLC, NedPower Mt. Storm, LLC, Kincaid Generation, LLC, State Line Energy, LLC, Fowler Ridge Wind Farm LLC, Virginia Electric and Power Company.

Description: Market Power Analyses Revised Appendix of Assets of Dominion Resources Services, Inc.

Filed Date: 06/10/2011.

Accession Number: 20110610–5223.

Comment Date: 5 p.m. Eastern Time on Friday, July 01, 2011.

Docket Numbers: ER11–3807–000.

Applicants: Xcel Energy Services Inc.

Description: Notice of Termination of the Engineering and Procurement Agreement between Basin Electric Power Cooperative and Northern States Power Company, FERC Electric Tariff Second Revised Volume No. 3. Service Agreement No. 280–NSP.

Filed Date: 06/15/2011.

Accession Number: 20110615–5138.

Comment Date: 5 p.m. Eastern Time on Wednesday, July 06, 2011.

Docket Numbers: ER11–3808–000.

Applicants: ORNI 39, LLC.

Description: ORNI 39, LLC submits tariff filing per 35.12: Petition of ORNI 39 LLC For Approval of Initial Market-Based Rate Tariff to be effective 8/1/2011.

Filed Date: 06/16/2011.

Accession Number: 20110616–5019.

Comment Date: 5 p.m. Eastern Time on Thursday, July 07, 2011.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES11–38–000.

Applicants: Upper Peninsula Power Company.

Description: Upper Peninsula Power Company's Application for Authorization to Issue Securities Under Section 204 of the Federal Power Act.

Filed Date: 06/15/2011.

Accession Number: 20110615–5134.

Comment Date: 5 p.m. Eastern Time on Wednesday, July 06, 2011.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF11–274–000.

Applicants: CraftMaster Manufacturing, Inc.

Description: Form 556—Notice of self-certification of qualifying cogeneration facility status of CraftMaster Manufacturing, Inc.

Filed Date: 05/20/2011.

Accession Number: 20110520–5101.

Comment Date: None Applicable.

Docket Numbers: QF11–276–000.

Applicants: Iowa Combined Heat and Power LLC.

Description: Form 556—Notice of self-certification of qualifying cogeneration facility status of Iowa Combined Heat and Power LLC.

Filed Date: 05/20/2011.

Accession Number: 20110520–5164.

Comment Date: None Applicable.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying

facility. Intervention and/or protest do not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets other than self-certifications and self-recertifications.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 16, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–15545 Filed 6–21–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC11–86–000.
Applicants: Shirley Wind, LLC, Shirley Wind (Delaware), LLC, DEGS Wind I, LLC.
Description: Application for Order Authorizing Disposition of Jurisdictional Facilities under Section 203 of the Federal Power Act of Shirley Wind, LLC, Shirley Wind (Delaware), LLC, and DEGS Wind I, LLC.
Filed Date: 06/03/2011.
Accession Number: 20110603–5239.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: EC11–87–000.
Applicants: Lakefield Wind Project, LLC, LWP Lessee, LLC.
Description: Joint Application of Lakefield Wind Project, LLC, and LWP Lessee, LLC for Authorization under Section 203 of the Federal Power Act and Request for Expedited Consideration.
Filed Date: 06/03/2011.
Accession Number: 20110603–5308.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG11–88–000.
Applicants: Tanner Street Generation, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Tanner Street Generation, LLC.
Filed Date: 05/31/2011.
Accession Number: 20110531–5213.
Comment Date: 5 p.m. Eastern Time on Tuesday, June 21, 2011.

Docket Numbers: EG11–89–000.
Applicants: LWP Lessee, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of LWP Lessee, LLC.
Filed Date: 06/03/2011.
Accession Number: 20110603–5244.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER07–1356–018; ER07–1112–017; ER07–1113–018; ER07–1116–016; ER07–1117–019; ER07–1358–020; ER07–1118–017; ER00–2885–037; ER01–2765–036; ER09–609–009; ER09–1141–016; ER05–1232–036; ER02–2102–036; ER03–1283–027.
Applicants: BE Alabama LLC, BE Allegheny LLC, BE CA LLC, BE Ironwood LLC, BE KJ LLC, BE Louisiana LLC, BE Rayle LLC, Cedar Brakes I, L.L.C., Cedar Brakes II, L.L.C., Centra Power & Lime, LLC, J.P. Morgan Commodities Canada Corporation, J.P. Morgan Ventures Energy Corporation, Utility Contract Funding, L.L.C., Vineland Energy LLC.
Description: JPMorgan Sellers Notice of Non-Material Change in Status re: Penta Wind, LLC under ER07–1356, *et al.*
Filed Date: 05/31/2011.
Accession Number: 20110531–5240.
Comment Date: 5 p.m. Eastern Time on Tuesday, June 21, 2011.

Docket Numbers: ER10–78–003.
Applicants: Orange Grove Energy, L.P.
Description: J-Power North America Holding Co., Ltd. Notification of Non-Material Change in Status.
Filed Date: 05/31/2011.
Accession Number: 20110531–5241.
Comment Date: 5 p.m. Eastern Time on Tuesday, June 21, 2011.

Docket Numbers: ER10–2631–001; ER10–2632–001.
Applicants: Tiverton Power Inc., Rumford Power Inc.
Description: Notice of Change in Status Regarding Market-Based Rate Authority of Rumford Power Inc., *et al.*
Filed Date: 06/03/2011.
Accession Number: 20110603–5294.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–1981–001.
Applicants: Alcan Power Marketing, Inc.
Description: Amendment to April 8, 2011 Filing of Alcan Power Marketing, Inc.
Filed Date: 06/03/2011.
Accession Number: 20110603–5223.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–2054–002.
Applicants: Ameren Illinois Company.
Description: Ameren Illinois Company submits tariff filing per 35: Compliance Filing for Ameren Illinois—Rate Schedule 112 to be effective 6/4/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5005.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–2093–002.
Applicants: Ameren Illinois Company.
Description: Ameren Illinois Company submits tariff filing per 35: Compliance Filing for Ameren Illinois—Rate Schedules 102, 103, 116 to be effective 6/4/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5006.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–2148–001.
Applicants: Ameren Illinois Company.
Description: Ameren Illinois Company submits tariff filing per 35: Compliance Filing for Ameren Illinois—Rate Scheds 100, 104, 106, 109, 111, 118 to be effective 6/3/2011.
Filed Date: 06/03/2011.

Accession Number: 20110603–5007.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–2180–001.
Applicants: Ameren Illinois Company.
Description: Ameren Illinois Company submits tariff filing per 35: Compliance Filing for Ameren Illinois—Rate Schedules 107, 117, 121, 122 to be effective 6/4/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5008.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–2184–001.
Applicants: Ameren Illinois Company.
Description: Ameren Illinois Company submits tariff filing per 35: Compliance Filing for Ameren Illinois—Rate Schedules 105, 110, 131 to be effective 6/4/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5011.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3679–000.
Applicants: Duke Energy Indiana, Inc.
Description: Notice of Cancellation of Duke Energy Corporation.
Filed Date: 06/03/2011.
Accession Number: 20110603–5331.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3695–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii: Errata to the PJM Tariff Attachment DD Section 8.4, to be effective 2/1/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5002.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3696–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii: Quarterly Updates to PJM Operating Agreement and RAA Membership List, to be effective 6/1/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5003.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3697–000.
Applicants: Southern California Edison Company.
Description: Southern California Edison Company submits tariff filing per 35.13(a)(1): Transmission Owner Tariff Transmission Rate Filing (TO6), to be effective 8/1/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5004.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3698–000.
Applicants: ISO New England Inc.
Description: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii: Filing of Chges. Related to Participant Affiliates to be effective 8/2/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5013.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3699–000.
Applicants: Power Exchange Corporation.
Description: Power Exchange Corporation submits tariff filing per 35.15: Power Exchange Corporation MBR Cancellation to be effective 6/6/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5016.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3700–000.
Applicants: California Independent System Operator Corporation.
Description: California Independent System Operator Corporation submits tariff filing per 35: 2011–06–03 CAISO's Tariff Waiver Filing to be effective N/A.
Filed Date: 06/03/2011.
Accession Number: 20110603–5017.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3701–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii: Queue No. W2–083; Original Service Agreement No. 2930 to be effective 5/10/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5018.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3702–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii: Queue No. W2–088; Original Service Agreement No. 2929 to be effective 5/10/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5019.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3703–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: Cancellation MISO–EKPC Redispatch Agreement to be effective 8/1/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5022.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3704–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: TOs Attachment O and MM Filing to be effective 7/1/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5023.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3705–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii: Queue No. W1–132; Original Service Agreement No. 2936 to be effective 5/10/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5024.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3706–000.
Applicants: Wisconsin Electric Power Company.
Description: Notice of Cancellation of Wisconsin Electric Power Company.
Filed Date: 05/31/2011.
Accession Number: 20110531–5199.
Comment Date: 5 p.m. Eastern Time on Tuesday, June 21, 2011.

Docket Numbers: ER11–3707–000.
Applicants: Wisconsin Electric Power Company.
Description: Notice of Cancellation of Wisconsin Electric Power Company.
Filed Date: 05/31/2011.
Accession Number: 20110531–5200.
Comment Date: 5 p.m. Eastern Time on Tuesday, June 21, 2011.

Docket Numbers: ER11–3708–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii: Queue No. W2–091; Original Service Agreement No. 2931 to be effective 5/10/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5036.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3709–000.
Applicants: PacifiCorp.
Description: PacifiCorp submits tariff filing per 35.13(a)(2)(iii: Deseret Control Area Services Agreement to be effective 7/31/2011.
Filed Date: 06/03/2011.

Accession Number: 20110603–5040.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3710–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii: Amendment to Attachment AE of the Tariff, to be effective 12/1/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5041.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3711–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii: Incorporation of Tri-County Electric Cooperative Formula Rate Template to be effective 8/1/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5043.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3712–000.
Applicants: Florida Power & Light Company.
Description: Florida Power & Light Company submits tariff filing per 35.12: FPL and Seminole Electric Cooperative, Inc. Service Agreement No. 223 to be effective 8/2/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5045.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3713–000.
Applicants: California Independent System Operator Corporation.
Description: California Independent System Operator Corporation submits tariff filing per 35: 2011–06–03 CAISO's BCR Tariff Waiver Filing to be effective N/A.
Filed Date: 06/03/2011.
Accession Number: 20110603–5046.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3714–000.
Applicants: Bridgeport Energy, LLC.
Description: Bridgeport Energy, LLC submits tariff filing per 35: Bridgeport Energy LLC to be effective 4/29/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5049.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3715–000.
Applicants: Morris Cogeneration, LLC.
Description: Morris Cogeneration, LLC submits tariff filing per 35: Morris Cogeneration, LLC's Notice of Change in Status Market-Based Rate Filing to be effective 4/29/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5050.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3716–000.
Applicants: Manchief Power Company LLC.
Description: Manchief Power Company LLC submits tariff filing per 35: Manchief Power Company LLC's Notice of Change in Status Market-Based Rate Filing to be effective 4/29/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5058.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3717–000.
Applicants: Frederickson Power L.P.
Description: Frederickson Power L.P. submits tariff filing per 35: Frederickson Power L.P.'s Notice of Change in Status Market-Based Rate Filing to be effective 4/29/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5064.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3718–000.
Applicants: CPIDC, Inc.
Description: CPIDC, Inc. submits tariff filing per 35: CPIDC, Inc.'s Notice of Change in Status Market-Based Rate Filing to be effective 4/29/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5072.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3719–000.
Applicants: Kansas City Power & Light Company.
Description: Kansas City Power & Light Company submits tariff filing per 35.13(a)(2)(iii: KCP&L Rate Schedule 135 to be effective 8/1/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5075.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3720–000.
Applicants: CPI USA North Carolina LLC.
Description: CPI USA North Carolina LLC submits tariff filing per 35: CPI USA North Carolina LLC's Notice of Change in Status Market-Based Rate Filing to be effective 4/29/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5078.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3721–000.
Applicants: Westar Energy, Inc.
Description: Westar Energy, Inc. submits tariff filing per 35.13(a)(2)(iii: City of Arma, Kansas to be effective 5/1/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5082.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3722–000.
Applicants: Westar Energy, Inc.
Description: Westar Energy, Inc. submits tariff filing per 35.13(a)(2)(iii: Burlingame, KS & Osage City, KS to be effective 5/1/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5086.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3723–000.
Applicants: TrueLight Energy, LLC.
Description: TrueLight Energy, LLC submits tariff filing per 35.12: TrueLight Energy MBRA Application to be effective 7/1/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5154.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3724–000.
Applicants: TrueLight Commodities, LLC.
Description: TrueLight Commodities, LLC submits tariff filing per 35.12: TrueLight Commodities MBRA Application to be effective 7/1/2011.
Filed Date: 06/03/2011.
Accession Number: 20110603–5157.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: ER11–3728–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator, Inc. Section 205 Filing to Seek Transitional Waiver of Provisions of its Tariff.
Filed Date: 06/03/2011.
Accession Number: 20110603–5328.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES11–36–000.
Applicants: The United Illuminating Company.
Description: Application of The United Illuminating Company for Authorization Under Section 204 of the Federal Power Act to Issue Short-Term Debt and Request for Expedited Treatment.
Filed Date: 06/03/2011.
Accession Number: 20110603–5125.
Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern

time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying facility. Intervention and/or protest do not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets other than self-certifications and self-recertifications.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 6, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–15549 Filed 6–21–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL11–44–000]

Iberdrola Renewables, Inc., PacifiCorp, NextEra Energy Resources, LLC, Invenergy Wind North America LLC, Horizon Wind Energy LLC v. Bonneville Power Administration; Notice of Complaint

Take notice that on June 13, 2011, pursuant to sections 210, 211A, 212, 307, 308, and 309 of the Federal Power Act (FPA), and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 386.206 (2011), Iberdrola Renewables, Inc., PacifiCorp, NextEra Energy Resources, LLC, Invenergy Wind North America LLC, and Horizon Wind Energy LLC (Complainants) filed a formal complaint against Bonneville Power Administration (Respondent or Bonneville) requesting that the Commission use its authority under FPA sections 210, 211A and 212 to order Bonneville to provide transmission services on terms and conditions that are comparable to those under which Bonneville provides transmission services to itself and that are not unduly discriminatory or preferential.

Complainants certify that copies of the complaint were served on the contacts for Bonneville as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on July 5, 2011.

Dated: June 15, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–15525 Filed 6–21–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL11–39–000]

Gregory R. Swecker, Beverly F. Swecker v. Midland Power Cooperative, State of Iowa; Notice of Amendment to Complaint

Take notice that on June 6, 2011, Gregory R. Swecker and Beverly F. Swecker (Complainants) filed an amendment to the petition originally filed on May 6, 2011, requesting that the Federal Energy Regulatory Commission (Commission) enforce certain requirements of Public Utility Regulatory Policies Act (PURPA) against Midland Power Cooperative and the State of Iowa (Respondents), alleging that Respondents failed to implement the Commission regulations by acting in direct contravention of said statutes, rules, orders and other laws administered by the Commission and the U.S. Supreme Court.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214).

Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on June 27, 2011.

Dated: June 15, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–15524 Filed 6–21–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP11–491–000]

Transcontinental Gas Pipe Line Company, LLC; Notice of Request Under Blanket Authorization

Take notice that on May 23, 2011 Transcontinental Gas Pipe Line Company, LLC (Transco), Post Office Box 1396, Houston, TX 77251, filed in the above Docket, a prior notice request pursuant to sections 157.205 and 157.216 of the Commission's regulations under the Natural Gas Act (NGA) and Transco's authorization in Docket No. CP82–426–000, for authorization to abandon in place: (i) Approximately 8.45 mile, 12-inch pipeline extending from South Marsh Island Block 38 to South Marsh Island Block 23, (ii) approximately 0.455 mile, 12-inch pipeline extending from production platform B in South Marsh Island Block 33 to South Marsh Island Block 38, (iii) and related metering facilities at South Marsh Island Block 33 and appurtenant facilities, collectively referred as the SMI Facilities, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions concerning this application may be directed to Nan Miksovsky, Transcontinental Gas Pipe Line Company, LLC, P.O. Box 1396, Houston, Texas, 77251 at (713) 215–3422.

Any person may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention. Any person filing to intervene or the Commission's staff may, pursuant to section 157.205 of the Commission's Regulations under the Natural Gas Act (NGA) (18 CFR 157.205) file a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

Dated: June 6, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–15547 Filed 6–21–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TS11–5–000]

Bangor Hydro Electric Company; Notice of Request for Waiver

Take notice that on June 13, 2011, pursuant to section 358.1(d) of the Commission's regulations, 18 CFR 358.1(d) (2011), Bangor Hydro Electric Company (Bangor Hydro) requests a limited waiver of Part 358 of the Commission's Regulations, Standards of Conduct for Transmission Providers (Standards of Conduct) adopted by the Commission in Order No. 717.[1]

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

[1] *Standards of Conduct for Transmission Providers, FERC Stats. & Regs.* ¶ 31,280 (2008) (Order No. 717), *order on reh'g,* FERC Stats. & Regs. ¶ 31,297 (2009) (Order No. 717–A), *order on reh'g,* 129 FERC ¶61,123 (Order No. 717–B), *order on reh'g,* 131 FERC ¶ 61,045 (2010) (Order No. 717–C) , *order on reh'g,* 135 FERC ¶ 61,017 (2011) (Order No. 717–D).

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on June 23, 2011.

Dated: June 15, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–15523 Filed 6–21–11; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9322–7; Docket ID No. EPA–HQ–ORD–2009–0398]

Toxicological Review of Methanol (Non-Cancer): In Support of Summary Information on the Integrated Risk Information System (IRIS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period on draft addendum and peer review workshop.

SUMMARY: On April 18, 2011, EPA released the external peer review draft human health assessment titled ''Toxicological Review of Methanol (Non-Cancer): In Support of Summary Information on the Integrated Risk Information System (IRIS)'' (EPA/635/R–11/001) for public comment. The public comment period ended June 17, 2011. EPA is releasing an addendum to the draft Toxicological Review of Methanol (Non-Cancer) and announcing a 14-day public comment period for the addendum.

The purpose of this addendum is to provide the public with several recent studies that were published between the initial release of the methanol assessment in January 2010 and the recent re-release of the non-cancer portion of that assessment in April 2011. Due to the unusual step of placing the methanol assessment on hold (as described in the April 18, 2011 **Federal Register** Notice), and the length of time that elapsed since the initial release of the assessment, EPA decided to issue the addendum addressing additional studies. Description and analyses of these studies are included as an addendum to the draft Toxicological Review that is now available on EPA's Web site (see below for details).

The draft Toxicological Review and the draft addendum were prepared by the National Center for Environmental Assessment (NCEA) within the EPA Office of Research and Development (ORD). EPA is releasing the draft addendum solely for the purpose of pre-dissemination peer review and public comment under applicable information quality guidelines. This draft assessment has not been formally disseminated by EPA. It does not represent and should not be construed to represent any Agency policy or determination.

EPA is also announcing that Eastern Research Group, Inc. (ERG), an EPA contractor for external scientific peer review, will convene an independent panel of experts and organize and conduct an external peer review workshop to review the draft Toxicological Review of Methanol (Non-Cancer), including the addendum. ERG invites the public to register to attend this workshop as observers. In addition, ERG invites the public to give brief oral comments and/or provide written comments at the workshop regarding the draft assessment under review. Space is limited, and reservations will be accepted on a first-come, first-served basis. In preparing a final report, EPA will consider the ERG report of the comments and recommendations from the external peer review workshop and any written public comments that EPA receives in accordance with the April 18, 2011, Notice and this Notice.

DATES: The public comment period on the draft addendum to the Toxicological Review of Methanol (Non-Cancer) begins June 22, 2011, and ends July 6, 2011. Comments should be in writing and must be received by EPA by July 6, 2011.

The peer review panel workshop on the Toxicological Review of Methanol (Non-Cancer) will be held on July 22, 2011, beginning at 8:30 a.m. and ending at 5 p.m. Eastern Time.

ADDRESSES: The draft addendum to the ''Toxicological Review of Methanol (Non-Cancer): In Support of Summary Information on the Integrated Risk Information System (IRIS)'' is available primarily via the Internet on the NCEA home page under the Recent Additions and Publications menus at *http://www.epa.gov/ncea.* A limited number of paper copies are available from the Information Management Team (Address: Information Management Team, National Center for Environmental Assessment [Mail Code: 8601P], U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone: 703–347–8561; facsimile: 703–347–8691). If you request a paper copy, please provide your name, mailing address, and the draft assessment title. Comments may be submitted electronically via *http://www.regulations.gov,* by e-mail, by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions provided in the **SUPPLEMENTARY INFORMATION** section of this notice.

The peer review workshop on the draft Toxicological Review of Methanol (Non-Cancer) will be held at Hilton Raleigh-Durham Airport at Research Triangle Park, 4810 Creek Lane, Durham, NC 27703. To attend the workshop, register no later than July 15, 2011, by calling Eastern Research Group, Inc., at 781–674–7374 or toll free at 800–803–2833 (ask for the Methanol peer review coordinator, Laurie Waite); sending a facsimile to 781–674–2906 (reference the ''Methanol Peer Review Workshop'' and include your name, title, affiliation, full address and contact information), or sending an e-mail to *meetings@erg.com* (reference the ''Methanol Peer Review Workshop'' and include your name, title, affiliation, full address and contact information). You can also register via the Internet at *https://www2.ergweb.com/projects/conferences/peerreview/register-toxmethanol.htm.* Space is limited, and reservations will be accepted on a first-come, first-served basis. There will be a limited time at the peer review workshop for comments from the public. Please inform ERG if you wish to make comments during the workshop.

Information on Services for Individuals with Disabilities: EPA welcomes public attendance at the ''Methanol Peer Review Workshop'' and will make every effort to accommodate persons with disabilities. For information on access or services for individuals with disabilities, contact ERG, 110 Hartwell Avenue, Lexington, MA 02421–3136 by calling 781–674–7374 or toll free at 800–803–2833 (ask for the Methanol peer review coordinator, Laurie Waite); sending a facsimile to 781–674–2906 (reference the ''Methanol Peer Review Workshop'' and include your name and contact information), or sending an e-mail to *meetings@erg.com* (reference the ''Methanol Peer Review Workshop'' and

include your name and contact information).

Additional Information

For information on the draft assessment, please contact Jeffrey Gift, PhD, U.S. Environmental Protection Agency, National Center for Environmental Assessment, Mail Code B243–01, 109 T.W. Alexander Drive, Durham, NC 27711; telephone: 919–541–4828; facsimile: 919–541–0245; or e-mail: *gift.jeff@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Information About IRIS

EPA's IRIS is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information for more than 540 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic noncancer health effects and cancer assessments. Combined with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health.

II. How To Submit Comments to the Docket at http://www.regulations.gov

Submit your comments, identified by Docket ID No. EPA–HQ–ORD–2009–0398, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: ORD.Docket@epa.gov.*
- *Facsimile:* 202–566–1753.
- *Mail:* Office of Environmental Information (OEI) Docket (Mail Code: 2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. The telephone number is 202–566–1752. If you provide comments by mail, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.
- *Hand Delivery:* The OEI Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202–566–1744. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by hand delivery, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

Instructions: Direct your comments to Docket ID No. EPA–HQ–ORD–2009–0398. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked ''late,'' and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at *http://www.regulations.gov,* including any personal information provided, unless comments include information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means that EPA will not know your identity or contact information unless you provide it in the body of your comments. If you send e-mail comments directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comments that are placed in the public docket and made available on the Internet. If you submit electronic comments, EPA recommends that you include your name and other contact information in the body of your comments and with any disk or CD–ROM you submit. If EPA cannot read your comments due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comments. 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, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

Dated: June 10, 2011.

David Bussard,

Acting Director, National Center for Environmental Assessment.

[FR Doc. 2011–15631 Filed 6–21–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2005–0220; FRL–8875–7]

Dicofol; Notice of Receipt of Request To Voluntarily Cancel Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of an irrevocable request by the registrants to voluntarily cancel their registrations of all products containing the pesticide dicofol. The request would terminate the last dicofol products registered for use in the United States. EPA intends to grant this request at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit further review of the request. If this request is granted, any sale, distribution, or use of products listed in this notice will be permitted after the registrations have been cancelled only if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments must be received on or before July 22, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2005–0220, by one of the following methods:

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

• *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2005–0220. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although, listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT:

Susan Bartow, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 603–0065; fax number: (703) 308–8090; e-mail address: *bartow.susan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

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

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background on the Receipt of Requests To Cancel and/or Amend Registrations To Delete Uses

This notice announces receipt by EPA of a request from registrants Agan Chemical Manufacturing, Ltd. and Makhteshim Agan of North America, Inc. to cancel dicofol product registrations. Dicofol is an organochlorine miticide which is registered for use on beans (dry, lima, and green), cotton, hops, mint, peppers, tomatoes, citrus, pecans, walnuts, tree nuts, cucurbits, grapes, pome fruit, stone fruit, strawberries, melons, and non-residential lawns and ornamentals. In a Memorandum of Agreement dated May 17, 2011, Agan Chemical Manufacturing, Ltd. and Makhteshim Agan of North America, Inc. requested that EPA cancel dicofol product registrations identified in Table 1 of Unit III. Specifically, the dicofol registrants requested cancellation of their technical product registration as of May 17, 2011. The dicofol registrants request cancellation of their end-use products, not to be effective before October 31, 2013. The dicofol registrants have agreed to cease all production of dicofol as of May 17, 2011, and to cease all sales and distribution of dicofol end-use products by October 31, 2013. The dicofol registrants also requested amendments to dicofol end-use product registrations to add a condition of registration that as of August 31, 2011,

the dicofol registrants will not sell or distribute dicofol end-use products that do not bear a prominent sticker prior to sale or distribution by the dicofol registrants that declares: ''It is unlawful to use this product after October 31, 2016.'' The Agency's action on the dicofol registrants' request will terminate the last dicofol products registered in the United States.

III. What action is the Agency taking?

This notice announces receipt by EPA of a request from registrants to cancel certain dicofol product registrations. The affected products and the registrants making the requests are identified in Tables 1 and 2 of this unit.

Unless the Agency determines that there are substantive comments that warrant further review of this request, EPA intends to issue an order canceling the affected registrations.

TABLE 1—DICOFOL PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Product name	Company
11603–26	Mitigan (Dicofol) Technical	Agan Chemical Manufacturing, Ltd.
66222–21	MANA Dicofol 4e	Makhteshim Agan of North America, Inc.
66222–56	Dicofol 4e	Makhteshim Agan of North America, Inc.
66222–95	Dicofol 50WSB	Makhteshim Agan of North America, Inc.

Table 2 of this unit includes the names and addresses of record for the registrants of the products listed in Table 1 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Table 1 of this unit.

TABLE 2—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION AND/OR AMENDMENTS

EPA Company No.	Company name and address
11603	Agan Chemical Manufacturing, Ltd., 4515 Falls of Neuse Road., Suite 300, Raleigh, North Carolina 27609.
66222	Makhteshim Agan of North America, Inc., 4515 Falls of Neuse Road, Suite 300, Raleigh, North Carolina 27609.

IV. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**.

Section 6(f)(1)(B) of FIFRA requires that before acting on a request for voluntary cancellation, EPA must provide a 30-day public comment period on the request for voluntary cancellation or use termination. In addition, FIFRA section 6(f)(1)(C) requires that EPA provide a 180-day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

1. The registrants request a waiver of the comment period, or

2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The dicofol registrants have requested that EPA waive the 180-day comment period. Accordingly, EPA will provide a 30-day comment period on the proposed requests.

V. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the action. If the request for voluntary cancellation is granted, the Agency intends to publish the cancellation order in the **Federal Register**.

In any order issued in response to this request for cancellation of product registrations, EPA proposes to include the following provisions for the treatment of any existing stocks of the products listed in Table 1 of Unit III.

Registrants of dicofol end-use products shall be allowed to sell and distribute existing stocks until October 31, 2013, and thereafter only for export consistent with the requirements of FIFRA section 17 or for purposes of proper disposal. Sale and distribution of existing stocks of any dicofol product by persons other than dicofol registrants shall be allowed until December 31, 2013, and thereafter only for products intended for export consistent with the requirements of FIFRA section 17 or for purposes of proper disposal. Use of existing stocks of any end-use product shall be allowed until October 31, 2016, and thereafter only for purposes of proper disposal.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: June 7, 2011.

Richard P. Keigwin Jr.,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

[FR Doc. 2011–15245 Filed 6–21–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. A copy of the agreement is available through the Commission's Web site (*http://www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 012130.

Title: Maersk Line/HLAG Latin America Slot Exchange Agreement.

Parties: A.P. Moller-Maersk A/S and Hapag-Lloyd AG.

Filing Parties: Wayne Rohde, *esq.;* Cozen O'Connor; 1627 I Street, NW.; Suite 1100; Washington, DC 20006.

Synopsis: The agreement would authorize the parties to exchange slots on their respective services in the trade between U.S. Gulf Coast and Brazil, Colombia, Jamaica, Panama, and Trinidad-Tobago.

By Order of the Federal Maritime Commission.

Dated: June 17, 2011.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2011–15622 Filed 6–21–11; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 15, 2011.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) P.O. Box 55882, Boston, Massachusetts 02106–2204:

1. *BSB Bancorp, Inc., Belmont, Massachusetts,* to acquire 100 percent of the outstanding capital stock of Belmont Savings Bank, Belmont, Massachusetts.

B. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Carlile Bancshares, Inc., Fort Worth, Texas,* to acquire 100 percent of the common stock of The Bank at Broadmoor, Colorado Springs, Colorado.

Board of Governors of the Federal Reserve System, June 16, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–15451 Filed 6–21–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 18, 2011.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Acting Vice President) 1000 Peachtree Street, NE., Atlanta, Georgia 30309:

1. *Commerce Union Bancshares, Inc.,* Springfield, Tennessee; to become a bank holding company by acquiring 100 percent of the voting shares of Commerce Union Bank, Springfield, Tennessee.

Board of Governors of the Federal Reserve System.

Dated: June 17, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–15614 Filed 6–21–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies That Are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

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 July 7, 2011.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *The Northern Trust Company and Northern Trust Corporation,* both located in Chicago, Illinois; to acquire 100 percent of the voting shares of Omnium LLC, Chicago, Illinois, and thereby engage in fund administration activities, pursuant to Board Order, *Societe Generale,* 84 Federal Reserve Bulletin 680 (1998).

Board of Governors of the Federal Reserve System.

Dated: June 17, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–15615 Filed 6–21–11; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation; Medicare Program; Meeting of the Technical Advisory Panel on Medicare Trustee Reports

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces public meetings of the Technical Advisory Panel on Medicare Trustee Reports (Panel). Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). The Panel will discuss the short-term (10 year) projection methods and assumptions in projecting Medicare health spending for Parts A, B, C and D and may make recommendations to the Medicare Trustees on how the Trustees might more accurately estimate health spending in the short run. The Panel's discussion is expected to be very technical in nature and will focus on the actuarial and economic assumptions and methods by which Trustees might more accurately measure health spending. Although panelists are not limited in the topics they may discuss, the Panel is not expected to discuss or recommend changes in current or future Medicare provider payment rates or coverage policy.

DATES: July 7, 2011, 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at HHS headquarters at 200 Independence Ave., SW., Washington, DC 20201, Room 738G.

Comments: The meeting will allocate time on the agenda to hear public comments at the end of the meeting. In lieu of oral comments, formal written comments may be submitted for the record to Donald T. Oellerich, OASPE, 200 Independence Ave., SW., Washington, DC 20201, Room 405F. Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Donald T. Oellerich (202) 690–8410, *Don.oellerich@hhs.gov. Note:* Although the meeting is open to the public, procedures governing security procedures and the entrance to Federal buildings may change without notice. Those wishing to attend the meeting must call or e-mail Dr. Oellerich by Friday July 1, 2011, so that their name may be put on a list of expected attendees and forwarded to the security officers at HHS Headquarters.

SUPPLEMENTARY INFORMATION: Topics of the Meeting: The Panel is specifically charged with discussing and possibly making recommendations to the Medicare Trustees on how the Trustees might more accurately estimate health spending in the United States. The discussion is expected to focus on highly technical aspects of estimation involving economics and actuarial science. Panelists are not restricted, however, in the topics that they choose to discuss.

Procedure and Agenda: This meeting is open to the public. The Panel will likely hear presentations by panel members and HHS staff regarding short range projection methods and assumptions. After any presentations, the Panel will deliberate openly on the topic. Interested persons may observe the deliberations, but the Panel will not hear public comments during this time. The Panel will also allow an open public session for any attendee to address issues specific to the topic.

Authority: 42 U.S.C. 217a; Section 222 of the Public Health Services Act, as amended. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Sherry Glied,

Assistant Secretary for Planning and Evaluation.

[FR Doc. 2011–15515 Filed 6–21–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority for the U.S. Department of Health and Human Services is being amended at Chapter AA, Immediate Office of the Secretary, as last amended at 76 FR 4703, dated, January 26, 2011, and at Chapter AQ, Office of Global Health Affairs (OGHA), as last amended at 69 FR 51679–80, dated August 20, 2004, as follows:

I. Under Part A, Chapter AA, Section AA.10 Organization, replace ''Office of Global Health Affairs (AQ)'' with ''Office of Global Affairs (AQ).''

II. Under Part A, Chapter AQ, replace all references to the ''Office of Global Health Affairs'' with ''Office of Global Affairs'' and all references to ''OGHA'' with ''OGA.''

III. Delegation of Authority. All delegations and redelegations of authority made to officials and employees of the Office of Global Affairs will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

Dated: June 14, 2011.

E.J. Holland, Jr.,

Assistant Secretary for Administration.

[FR Doc. 2011–15517 Filed 6–21–11; 8:45 am]

BILLING CODE 4110–60–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Insulin Delivery and Glucose Monitoring Devices for Diabetes Mellitus

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for scientific information submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from medical device manufacturers of insulin pumps and continuous glucose monitors. Scientific information is being solicited to inform our Comparative Effectiveness and Safety of Insulin Delivery and Glucose Monitoring Methods for Diabetes Mellitus review, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173.

DATES: Submission Deadline on or before July 22, 2011.

ADDRESSES: *Online submissions: http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/.* Please select the study for which you are submitting information from the list of current studies and complete the form to upload your documents.

E-mail submissions: ehcsrc@ohsu.edu. Print submissions: Robin Paynter, Oregon Health and Science University, Oregon Evidence-based Practice Center,

3181 SW Sam Jackson Park Road, Mail Code: BICC, Portland, OR 97239–3098.

FOR FURTHER INFORMATION CONTACT: Robin Paynter, Research Librarian, Telephone: 503–494–0147 or E-mail: *ehcsrc@ohsu.edu.*

SUPPLEMENTARY INFORMATION: In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, the Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for the Effectiveness and Safety of Insulin Delivery and Glucose Monitoring Methods for Diabetes Mellitus.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by systematically requesting information (*e.g.* details of studies conducted) from medical device industry stakeholders through public information requests, including via the **Federal Register** and direct postal and/or online solicitations. We are looking for studies that report on the Comparative Effectiveness and Safety of Insulin Delivery and Glucose Monitoring Methods for Diabetes Mellitus, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: *http://effectivehealthcare.AHRQ.gov/index.cfm/search-for-guides-reviews-and-reports/?PAGEaction=displayproduct&productid=689.*

This notice is a request for industry stakeholders to submit the following:

- A current product label, if applicable (preferably an electronic PDF file).
- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.
- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results. Registered *ClinicalTrials.gov* studies. Please provide a list including the *ClinicalTrials.gov* identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

The draft of this review will be posted on AHRQ's EHC program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: *http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/.*

Key Questions

Our draft Key Questions (KQs) were posted for public comment in October 2010 (see Appendix 1). Based on the public comments, we made the following changes to the KQs:

1. We will not include pregnant women with gestational diabetes in the review. There is a range of glucose abnormalities among women with gestational diabetes, and many women with gestational diabetes are not on intensive insulin therapy. Insulin pump therapy and CGM are more relevant to pregnant women with pre-existing diabetes. The population for this review will include patients with type 1 diabetes, patients with type 2 diabetes who are on insulin therapy, and pregnant women with pre-existing diabetes.

2. We will see if there are any studies that focused on older adults (age >65 years). Currently, there is no upper age limit on our proposed study populations, so we should be able to examine this group if data are available. Therefore, the age categories considered for this review will be very young children, adolescents and adults, including older adults (age >65 years).

3. KQ3 was made a subquestion of KQ 2.

There were several other relevant comments about the KQs and the protocol. These comments and our responses are summarized below.

1. We plan to abstract the following data to use in our analysis when available: measurement of adherence, MDI delivery method (pen vs. vial or syringe), study design, information about device use (e.g., analyses based on adherence to wearing the device, training of patient/staff, generation/model of devices), study participant characteristics, adjustment to insulin therapy, definitions of hypoglycemia, definitions of diabetes, assessment of quality of life, rt-CGM alarm threshold, and study length and followup time.

2. Because insulin regimens may change over time, it may be difficult to determine if the current delivery method is responsible for the long-term outcomes. Therefore, we will abstract data on the length of use of current technology, changes in the mode of insulin delivery over time, and changes in the type of insulin used over time if available.

3. The list of process measures and intermediate outcomes will not change. Some of the suggested outcomes were either beyond the scope of the review (e.g., changes in carbohydrate counting, diet, and physical activity) or only applied to a particular insulin-delivery device or blood glucose-monitoring technique (e.g., time spent in the hypoglycemic range).

The finalized KQs are:

KQ 1

In patients receiving intensive insulin therapy, does mode of delivery (multiple daily injections [MDI] vs. continuous subcutaneous insulin infusion [CSII]) have a differential effect on process measures, intermediate outcomes, and clinical outcomes in patients with diabetes mellitus? (Process measures, intermediate outcomes, and clinical outcomes of interest are summarized below in Table 1.) Do these effects differ by:

a. Type 1 or type 2 diabetes status?

b. Age: Very young children, adolescents, and adults, including older adults (age >65 years)?

c. Pregnancy status: Pre-existing type 1 or type 2 diabetes?

KQ 2

In patients using intensive insulin therapy (MDI or CSII), does the type of glucose monitoring (real-time continuous glucose monitoring [rt-CGM] vs. self-monitoring of blood glucose [SMBG]) have a differential effect on process measures, intermediate outcomes, and clinical outcomes (see Table 1) in patients with diabetes mellitus (*i.e.,* what is the incremental benefit of rt-CGM in patients already using intensive insulin therapy on process and outcome measures)? Do these effects differ by:

a. Type 1 or type 2 diabetes status?

b. Age: Very young children, adolescents, and adults, including older adults (age >65 years)?

c. Pregnancy status: Pre-existing type 1 or type 2 diabetes?

d. Intensive insulin delivery: MDI or CSII?

TABLE 1—SUMMARY OF PROCESS MEASURES AND INTERMEDIATE AND CLINICAL OUTCOMES

Process measures	Intermediate outcomes	Clinical outcomes

• Ratio of basal to bolus insulin
• Frequency of adjusting insulin therapy
• Adherence to insulin therapy/sensor use
• Frequency of professional or allied health visits.
	• Primary
	  • Hemoglobin $A1_c$
	• Secondary
	  • Hyperglycemia
	  • Weight gain
	  • Hypoglycemia frequency
		• Microvascular*
		  • Retinopathy
		  • Nephropathy
		  • Neuropathy
		• Macrovascular*
		  • Coronary heart disease
		  • Cerebrovascular disease
		  • Peropheral arterial disease
		• Severe hypoglycemia
		• Quality of life
		• Fetal outcomes †
		• Maternal pregnancy outcomes
		  • C-section rates

* We will only include objective assessments of microvascular and macrovascular outcomes (i.e., we will be excluding patient self-reported microvascular and macrovascular outcomes).

† Fetal outcomes include gestational age, birth weight, frequency of neonatal hypoglycemia, birth trauma, major and minor anomalies, and admission to a neonatal intensive care unit.

For each KQ we will identify:

Population(s):

Adults, adolescents, and children with type 1 or type 2 diabetes mellitus and pregnant women with pre-existing diabetes treated with insulin therapy.

1. We will use age ranges prescribed by the Juvenile Diabetes Research Foundation (<8 years [very young children], 8–14 years [children], 14–25 years [adolescent], and >25 years [adults]); however, our final definitions will be guided by those used in the literature that is reviewed.

2. If available, we will examine data among populations of older adult (>65 years).

Interventions:

The interventions of interest are CSII (see Appendix 2 for a list of insulin pumps and models) and rt-CGM (see Appendix 3 for a list of monitors).

1. We will not be including the following devices because they are no longer used in the United States:

a. GlucoWatch continuous glucose meter

b. Insulin pumps with regular insulin

Comparators:

All studies must have a concurrent comparison group.

1. CSII would be compared with MDI, which will be defined as at least three injections of basal and rapid-acting insulin per day.

2. rt-CGM would be compared with SMBG, which will be defined as at least three fingersticks per day.

Outcomes measures for each KQ:

1. Process measures

a. Ratio of basal to bolus insulin

b. Frequency of adjustments to insulin therapy

c. Adherence to insulin therapy/sensor use

d. Frequency of professional or allied health visits Intermediate outcomes

• HbA1c

a. Hyperglycemia

b. Weight gain

c. Hypoglycemia frequency

Clinical Outcomes

• Objective assessments of microvascular outcomes (retinopathy, nephropathy, and neuropathy)

a. Objective assessments of macrovascular outcomes (coronary heart disease, cerebrovascular disease, and peripheral arterial disease)

b. Severe hypoglycemia

c. Quality of life

d. Fetal outcomes (gestational age, birth weight, frequency of neonatal hypoglycemia, birth trauma, major and minor anomalies, and admission to a neonatal intensive care unit)

e. Maternal pregnancy outcomes (cesarean section rates)

Timing: Usage of a device for at least 24 hours.

Settings: Outpatient setting.

Dated: June 10, 2011.

Carolyn M. Clancy,

AHRQ, Director.

[FR Doc. 2011–15580 Filed 6–21–11; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0110]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Prescription Drug Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Prescription Drug Advertisements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 24, 2011 (76 FR 4117), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0686. The approval expires on June 30, 2014. A

copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: June 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–15592 Filed 6–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0464]

Draft Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption and Premarket Approval Applications for Low Glucose Suspend Device Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Draft Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Low Glucose Suspend (LGS) Device Systems.'' This draft guidance document provides industry and Agency staff with recommendations that are intended to improve the safety and effectiveness of LGS Device Systems. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 20, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Draft Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Low Glucose Suspend (LGS) Device Systems'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charles Zimliki, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2556, Silver Spring, MD 20993–0002, 301–796–6297.

SUPPLEMENTARY INFORMATION:

I. Background

Diabetes mellitus has reached epidemic proportions in the United States and more recently, worldwide. The morbidity and mortality associated with diabetes is anticipated to account for a substantial proportion of health care expenditures. Although there are many devices available that help patients manage the disease, FDA recognizes the need for new and improved devices for treatment of diabetes. One of the more advanced diabetes management systems is an artificial pancreas device system. An artificial pancreas system is a type of autonomous system that adjusts insulin infusion based upon the continuous glucose monitor via control algorithm. There are a variety of types of artificial pancreas systems depending upon the nature of the control algorithm. They can be generally divided into three categories, LGS, Treat-to-Range, and Treat-to-Target. In this notice, FDA is announcing a draft guidance for the first type of artificial pancreas, the LGS system. An LGS system links a continuous glucose monitor to an insulin pump and automatically reduces or suspends insulin infusion temporarily based upon specified thresholds of measured glucose levels. This type of system is designed to reduce or mitigate the likelihood of a hypoglycemic event. There are significant challenges in creating an autonomous system, which were discussed in a joint FDA and National Institutes of Health (NIH) artificial pancreas workshop on November 10, 2010 (information available at: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm226251.htm.* Currently, there is no FDA-approved artificial pancreas for home use. This workshop sought feedback on ways to overcome the obstacles towards developing an artificial pancreas. The feedback received from this workshop and the continued communication with investigators in this field has provided valuable input for FDA's first guidance for a LGS device. This guidance will outline considerations for development of clinical studies, and recommends elements that should be included in IDE and PMA applications, focusing on critical elements of safety and effectiveness for approval of this device type. The guidance includes one suggested approach to support safety and effectiveness, but given the early stage of this technology, FDA is open to considering alternative study design approaches and seeks comments regarding alternative approaches. FDA particularly seeks comments regarding the validity of the Continuous Glucose Monitor based event for hypoglycemia endpoint, pivotal study design, and patient population. As the LGS system is one of three types of artificial pancreas systems, comments to the LGS guidance will not only assist FDA in finalizing guidance on LGS systems, but also assist in developing future draft guidance for the other types of artificial pancreas systems. FDA continues to work with the investigators in this field and is developing a second guidance to address the remaining artificial pancreas device systems.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on LGS Device systems. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Draft Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket

Approval (PMA) Applications for Low Glucose Suspend (LGS) Device Systems,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1748 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 801 and 809 are currently approved under OMB control number 0910–0485, the collections of information in 21 CFR part 812 are currently approved under OMB control number 0910–0078, and the collections of information in 21 CFR part 814 are currently approved under OMB control number 0910–0231.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: June 16, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–15541 Filed 6–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0469]

Draft Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering To Optimize Medical Device Design; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Draft Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Optimize Medical Device Design.'' The recommendations in this guidance are intended to improve the safety and effectiveness of devices and reduce use error. This draft guidance is not final; nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by September 19, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Draft Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Optimize Medical Device Design'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Molly Story, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2533, Silver Spring, MD 20993–0002, 301–796–1456, e-mail: *molly.story@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

To understand use-related hazards, it is necessary to have an accurate and complete understanding of how a device will be used. Understanding and optimizing how people interact with technology is the subject of human factors engineering (HFE) and usability engineering (UE). HFE/UE considerations that are important to the development of medical devices include three major components of the device-user system: (1) Device users, (2) device use environments, and (3) device user interfaces.

For safety-critical technologies such as medical devices, the process of eliminating or reducing design-related use problems that contribute to or cause unsafe or ineffective medical treatment is part of a process for controlling overall risk. For devices where harm could result from ''use errors,'' the dynamics of user interaction are safety-related and should be components of risk analysis and risk management. By incorporating these considerations into the device development process, manufacturers can reduce the overall risk level posed by their devices, thus decreasing adverse events associated with the device, and avoid potential device recalls.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the Agency's current thinking on human factors engineering for medical devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability is available for all CDRH guidance documents at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. To receive ''Draft Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Optimize Medical Device Design.'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1757 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These

collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B are approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H are approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 801 are approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: June 17, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–15570 Filed 6–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0443]

Scientific Evaluation of Modified Risk Tobacco Product Applications; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Tobacco Products is announcing a public workshop to obtain input on specific issues associated with the scientific evaluation of modified risk tobacco product (MRTP) applications. The Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) establishes a requirement for persons to obtain an order from FDA before they can introduce or deliver for introduction into interstate commerce MRTPs and outlines the requirements that must be met before FDA will issue such an order. The Tobacco Control Act also directs FDA to get input from appropriate scientific and medical experts on the design and conduct of studies and surveillance required for assessment and ongoing review of MRTP applications. The purpose of the public workshop is to create a forum for appropriate scientific and medical experts and other interested stakeholders to provide input on these topics. FDA will take the information it obtains from the public workshop into account as it determines how best to implement the MRTPs provisions of the Tobacco Control Act. FDA is also opening a public docket to receive comments on these topics.

DATES: *Dates and Times:* The public workshop will be held on August 25, 2011, from 8:30 a.m. to 5:30 p.m., and on August 26, 2011, from 8:30 a.m. to 4 p.m. Individuals who wish to make a presentation at the public workshop must register by close of business on August 3, 2011. Submit either electronic or written comments to the docket by September 23, 2011.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: *Contact Person:* Anuja Patel, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373 (choose option 4), FAX: 240–276–3761, e-mail: *workshop.CTPOS@fda.hhs.gov.*

Registration to Attend the Workshop and Requests for Oral Presentation: If you wish to attend the workshop or make an oral presentation at the workshop, please e-mail your registration to *workshop.CTPOS@fda.hhs.gov* by close of business on August 3, 2011. Those without e-mail access may register by contacting Anuja Patel (*see Contact Person*). Please provide contact information for each attendee, including name, title, affiliation, address, e-mail address, and telephone number. Registration is free and will be on a first-come-first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the workshop will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing registration for the workshop at *http://www.fda.gov/TobaccoProducts/default.htm.*

An open comment session will be held during the public workshop on August 25, 2011, from 11 a.m. to 12:30 p.m., during which comments from the public will be accepted. If you would like to make an oral presentation during the open comment session, you must indicate this at the time of registration. FDA has included questions for comment in section II of this document. You should identify the question number(s) you will address in your presentation and the approximate time requested for your presentation.

FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Persons registered to make a formal presentation must check in at the registration table by 10 a.m. on August 25, 2011. In addition, we strongly encourage submitting comments to the docket (*see Comments*).

If you need special accommodations because of a disability, please contact Anuja Patel (see *Contact Person*) at least 7 days before the workshop.

Comments: Regardless of attendance at the public workshop, interested persons may submit comments on any questions for comment in section II of this document by September 23, 2011. Submit electronic comments to *http://www.regulations.gov.* Submit 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. It is no longer necessary to send two copies of mailed 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.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, President Obama signed into law the Tobacco Control Act, providing FDA with the authority to regulate tobacco products (Pub. L. 111–31; 123 Stat. 1776). The Tobacco Control Act amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 911 (21 U.S.C. 387k), which prohibits the introduction or delivery for introduction of an MRTP into interstate commerce without an order from FDA.

MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. According to section 911(b)(1) of the FD&C Act, a tobacco product is considered to be sold or distributed for use to reduce harm or the risk of tobacco-related disease if its label, labeling, or advertising represents, either explicitly or implicitly, that:

- The product is less harmful or presents a lower risk of tobacco-related disease than one or more commercially marketed tobacco products; or
- The product or its smoke contains a reduced level of, presents a reduced exposure to, or is free of a substance.

A tobacco product is also considered to be sold or distributed for use to reduce harm or the risk of tobacco-related disease if the product's:

- Label, labeling, or advertising uses the words ''light,'' ''mild,'' or ''low,'' or similar descriptors; or
- Manufacturer has taken any action after June 22, 2009, directed to consumers through the media or otherwise (other than through the product's label, labeling, or advertising) that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a reduced risk of harm, tobacco-related disease, or exposure to a substance than one or more commercially marketed tobacco products.

Section 911(b)(2) of the FD&C Act

Before an MRTP can be introduced or delivered for introduction into interstate commerce, an application for the product must be filed with FDA, and the Agency must review the application and determine whether it is appropriate to issue an order under section 911(g). (*See* section 911(a), (d), and (g) of the FD&C Act.) Section 911(d) of the FD&C Act describes the required contents of an MRTP application, while section 911(g) of the FD&C Act describes the requirements for obtaining an order.

Section 911(g) of the FD&C Act sets forth two bases for obtaining an order from FDA for an MRTP application. Under section 911(g)(1), FDA shall issue an order only if FDA determines that an applicant has demonstrated that the product, as it is actually used by consumers, will:

- Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users, and
- Benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.

Under section 911(g)(2), FDA may issue an order for MRTPs that may not satisfy the requirements under section 911(g)(1) (described previously) if FDA determines that an applicant has demonstrated that:

- Such an order would be appropriate to promote the public health;
- Any aspect of the label, labeling, and advertising for the product that would cause the product to be an MRTP is limited to an explicit or implicit representation that the tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;
- Scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards for an order set forth in section 911(g)(1) of the FD&C Act; and
- The scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies.

Furthermore, for FDA to issue an order under section 911(g)(2), FDA must find that the applicant has demonstrated that:

- The magnitude of overall reductions in exposure to the substance or substances that are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;
- The product as actually used by consumers will not expose them to higher levels of other harmful substances compared to similar types of tobacco products then on the market unless such increases are minimal, and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;
- Testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product is or has been demonstrated to be less harmful or presents or has been demonstrated to present less of a risk of disease than one or more other commercially marketed tobacco products; and
- Issuance of an order is expected to benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.

In making determinations regarding the benefit to the health of individuals and the population as a whole under section 911(g)(1) or (g)(2), FDA will take into account:

- The relative health risks the MRTP presents to individuals;
- The increased or decreased likelihood that existing tobacco product users who would otherwise stop using such products will switch to using the MRTP;
- The increased or decreased likelihood that persons who do not use tobacco products will start using the MRTP;
- The risks and benefits to persons from the use of the MRTP as compared to the use of smoking cessation drug or device products approved by FDA to treat nicotine dependence; and
- Comments, data, and information submitted to FDA by interested persons.

Section 911(g)(4) of the FD&C Act

Each applicant receiving an order from FDA under section 911(g)(1) or (g)(2) will conduct postmarket surveillance and studies, either as a condition of receiving an order under section 911(g)(2), or as required by FDA for products receiving an order under section 911(g)(1). (*See* section 911(g)(2)(C)(ii) and 911(i)(1) of the FD&C Act.)

Section 911(h) of the FD&C Act describes additional conditions for marketing MRTPs. For example, under section 911(h)(1) of the FD&C Act, the advertising and labeling of an MRTP must enable the public to comprehend the information concerning modified risk and understand the relative significance of such information in the context of total health and in relation to all the diseases and health-related conditions associated with the use of tobacco products. Under section 911(h)(2) of the FD&C Act, FDA may require that a claim comparing an MRTP

to one or more commercially marketed tobacco products compare the MRTP to a commercially marketed tobacco product that is representative of that type of tobacco product on the market. Under that section, FDA may also require that the identity of the reference tobacco product and the percentage change and a quantitative comparison of the amount of the substance claimed to be reduced be stated in immediate proximity to the most prominent claim. Under section 911(h)(3) of the FD&C Act, FDA may require that an MRTP's label disclose other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that may affect a disease or health-related condition or increase the risk of other diseases or health-related conditions associated with the use of tobacco products. Under that section, FDA may also require an applicant to label the product with conditions of use if the conditions of use may affect the risk of the product to human health. Section 911(h)(4) of the FD&C Act requires than an order issued under section 911(g)(1) of the FD&C Act be effective for a specified period of time. Furthermore, under section 911(h)(5) of the FD&C Act, FDA may require that MRTPs that are granted an order under section 911(g)(1) of the FD&C Act comply with requirements relating to advertising and promotion of the product.

Section 911(l) of the FD&C Act requires FDA to issue regulations or guidance (or any combination thereof) regarding the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Among other things, the regulations or guidance must:

- To the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under section 911(g) to show that a substantial reduction in morbidity or mortality among individual tobacco users occurs (under 911(g)(1)) or is reasonably likely (under 911(g)(2));
- Include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;
- Establish minimum standards for postmarket studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate; and
- Establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception.

Section 911(l) of the FD&C Act

Section 911(l)(2) of the FD&C Act directs FDA to get input from appropriate scientific and medical experts on the design and conduct of studies and surveillance required for assessment and ongoing review of modified risk tobacco products.

II. Workshop Objectives and Issues for Discussion

The purpose of this public workshop is to obtain information and comments from appropriate medical and scientific experts, which may include academia, public health groups, regulators, manufacturers of tobacco products, health care professionals, interested industry, and professional associations, and the public about the scientific issues associated with assessment and ongoing review of MRTPs. The input from the public workshop is expected to provide valuable information to assist the Agency in developing guidance or regulations.

At the public workshop, FDA will provide relevant background information, including a brief summary of section 911 of the FD&C Act, as added by the Tobacco Control Act. The meeting will include scientific and medical expert speakers who will present on scientific and technical factors related to the evaluation of MRTPs. FDA anticipates that the key questions that will be considered at the public workshop are those listed in the paragraphs that follow. FDA is interested in receiving substantive scientific input on these questions at the meeting and in the docket. FDA will post the agenda and additional workshop background material 5 days before the workshop at: *http://www.fda.gov/TobaccoProducts/default.htm.*

A. Benefit to Individual Tobacco Users

Modified risk tobacco products have the potential to benefit individual tobacco users by reducing harm and the risk of tobacco-related disease compared to conventional tobacco products. FDA seeks comments and information on the following issues:

1. What scientific evidence would inform a determination that an MRTP, as actually used, will significantly reduce harm and the risk of tobacco-related disease to users? What types (if any) of scientific studies other than long-term epidemiological studies could show a significant reduction in harm and the risk of tobacco-related disease to users?

2. What scientific evidence would inform a determination that an MRTP, as actually used, presents a reasonable likelihood of a measurable and substantial reduction in tobacco-related morbidity or mortality among individual tobacco users?

B. Impact on the Health of the Population as a Whole

MRTPs may offer the potential for benefitting individual tobacco users by reducing the risk of tobacco-related morbidity or mortality associated with conventional tobacco products. However, these products could harm the health of the population as a whole if they lead to continued use of tobacco products in individuals who would otherwise have quit, resumption of tobacco use in individuals who previously quit (i.e., relapse), dual use among current tobacco users, or initiation of tobacco use among individuals who otherwise would not have used tobacco products. FDA seeks comments and information on the following issues related to the impact of an MRTP on the health of the population as a whole:

1. What scientific evidence would inform a determination of how an MRTP will actually be used by consumers once it is commercially marketed, and what are the strengths and limitations of different methods of studying actual consumer use?

2. What scientific evidence, including consumer perception data, would inform a determination of the effect an MRTP as it is proposed to be labeled and marketed will have on increasing initiation of tobacco use among non-users, decreasing or delaying cessation due to switching to the MRTP among current tobacco users, encouraging use of multiple tobacco products instead of complete switching among current tobacco users, and increasing relapse among previous tobacco users who have quit?

3. What scientific evidence would inform the measurement of potential benefits relative to potential harms to the general population to achieve an overall public health benefit?

C. Comparisons of MRTPs to Other Products

In making determinations regarding the benefit to the health of individuals and the population as a whole under either section 911(g)(1) or (g)(2), FDA will take into account, among other things, the relative health risks to individuals of the MRTP and the risks and benefits to users of the MRTP as compared to the use of smoking cessation drugs or devices approved to

treat nicotine dependence. (*See* section 911(g)(4) of the FD&C Act.) FDA seeks comments and information on the following issues:

1. What comparisons should be used in scientific studies intended to inform a determination of the effects of an MRTP on reducing the risk of tobacco-related disease to individual users relative to one or more commercially marketed tobacco products?

2. What comparisons should be used in scientific studies intended to inform a determination of the effects of an MRTP on reducing exposure to a harmful substance or substances?

3. What comparisons should be used in scientific studies intended to inform a determination of whether an MRTP will benefit or is likely to benefit the health of the population as a whole?

4. What scientific evidence would inform the evaluation of the risks and benefits of the use of an MRTP as compared to use of drug or device products approved to treat nicotine dependence?

D. Reduced Substance Exposure

Tobacco products are considered MRTPs if their label, labeling, or advertising represents, either explicitly or implicitly, that the product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance, or that the product or its smoke does not contain or is free of a substance. (*See* section 911(b)(2)(A)(i) of the FD&C Act.) For FDA to issue an order regarding an MRTP application under section 911(g)(2), FDA must determine that the applicant has demonstrated that, among other things, the magnitude of the overall reductions in exposure to the substance or substances that are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances. Moreover, FDA must determine that the applicant has demonstrated that the MRTP, as actually used by consumers, will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless the increases are minimal and the reasonably likely overall impact of the use of the MRTP remains a substantial and measurable reduction in overall morbidity and mortality. FDA seeks comments and information on the following issues:

1. What scientific evidence would inform a determination that an MRTP (or its smoke) does not contain or contains a reduced level of a substance?

2. What scientific evidence would inform a determination that the reduction in exposure to a substance presented by an MRTP is substantial?

3. What scientific evidence would inform a determination that an MRTP as it is actually used by consumers will expose consumers to the specified reduced level of a substance?

4. What scientific evidence would inform a determination that an MRTP does not increase exposure to other harmful substances? If an MRTP does increase exposure to another harmful substance, what scientific evidence would inform a determination that any increase is minimal and, overall, there is still a likelihood of a measurable and substantial reduction in morbidity and mortality among individual tobacco users?

E. Consumer Perception of MRTPs

To issue an order under section 911(g)(2), FDA must find that the applicant has demonstrated that testing of actual consumer perceptions of the tobacco product, as it is proposed to be labeled and marketed, shows that consumers will not be misled into believing that the product is or has been demonstrated to be less harmful or that it presents or has been demonstrated to present less risk of disease than one or more commercially marketed tobacco products. (*See* section 911(g)(2)(B)(iii) of the FD&C Act.) Furthermore, section 911(h)(1) requires FDA to ensure that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products. (*See* section 911(h)(1) of the FD&C Act.) FDA seeks comments and information on the following issues related to consumer perception:

1. What scientific evidence would inform a determination that consumers will not be misled by a representation that an MRTP or its smoke does not contain or contains a reduced level of a substance into believing that the product is or has been demonstrated to be less harmful, or presents, or has been demonstrated to present, less risk of disease than one or more other commercially marketed tobacco products?

2. What scientific evidence would inform a determination that consumers will comprehend the information concerning modified risk in an MRTP's advertising and labeling and understand the relative significance of such information in the context of total health and in relation to all the diseases and health-related conditions associated with the use of tobacco products?

F. Postmarket Surveillance and Studies of Commercially Marketed MRTPs

Each applicant receiving an order from FDA under section 911(g)(1) or (g)(2) will conduct postmarket surveillance and studies, either as a condition of receiving an order under section 911(g)(2), or as required for products receiving an order under section 911(g)(1). (See section 911(g)(2)(C)(ii) and 911(i)(1) of the FD&C Act.) Such surveillance and studies are designed to, among other things, determine the impact of an FDA order on consumer perception, behavior, and health, and enable FDA to review the accuracy of the determinations upon which the Agency based its order. (*See* section 911(g)(2)(C)(ii) and (i)(1) of the FD&C Act.) FDA seeks comments and information on the following issues related to postmarket surveillance and studies:

1. What types of postmarket studies could provide regular and long-term assessments of patterns of product use (*e.g.,* dual use, product switching) and the impact of the MRTP on quitting behavior, relapse, and initiation of tobacco use?

2. What types of postmarket studies could provide regular and long-term assessments of exposure levels to harmful substances?

3. What types of postmarket studies could provide regular and long-term assessments of applicable validated biomarkers and intermediate clinical endpoints?

4. What types of postmarket studies could provide regular and long-term assessments of health outcomes and mortality?

5. What types of postmarket studies could provide regular and long-term assessments of consumer perception of the MRTP and other tobacco products?

6. What types of postmarket surveillance (other than postmarket studies) could be used to ensure appropriate collection of data regarding the use, consumer perception, and health risks of an MRTP?

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (*see Comments*). A transcript will also be available in either hard copy or on CD–ROM, after submission of a

Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: June 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–15601 Filed 6–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 20 and 21, 2011, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1609, Silver Spring, MD 20993–0002, 301–796–6313, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On July 20, 2011, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the Edwards SAPIEN Transcatheter Heart Valve sponsored by Edwards Lifesciences. The Edwards SAPIEN™ Transcatheter Heart Valve, model 9000TFX, sizes 23 millimeters (mm) and 26 mm and accessories implant system consists of the following:

- The Edwards SAPIEN Transcatheter Heart Valve consists of a heterologous (bovine) pericardium leaflet valve sutured within a stainless steel mesh frame, with a polyester skirt. It is offered in 2 sizes, a 23 mm and a 26 mm.
- The RetroFlex 3 Delivery System is used to advance the bioprosthesis through the RetroFlex sheath over a guidewire and to track the bioprosthesis over the aortic arch and for crossing and positioning in the native valve. The delivery system also comes with a sheath, introducer, loader, dilator, balloon (used to pre-dilate the native annulus) and a crimper.

On July 21, 2011, the committee will discuss, make recommendations, and vote on information related to the humanitarian device exemption for the Berlin Heart EXCOR Pediatric Ventricular Assist Device (VAD) sponsored by Berlin Heart, Inc. The Berlin Heart EXCOR Pediatric VAD device is a pneumatically-driven extracorporeal ventricular assist device. It is designed to provide bridge-to-transplant mechanical support to the heart. The system consists of one or two extracorporeal blood pumps (univentricular or biventricular support), cannulae for the connection of the blood pumps to the atria and great arteries, and the IKUS Stationary Driving Unit (electro-pneumatic driving system).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 14, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 6, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 8, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301–796–5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: *June 15, 2011.*

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–15539 Filed 6–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0104 (Formerly Docket No. 2007E–0001)]

Determination of Regulatory Review Period for Purposes of Patent Extension; METVIXIA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for METVIXIA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA approved for marketing the human drug product METVIXIA (Methyl aminolevulinate hydrochloride). METVIXIA is indicated for treatment of thin and moderately thick, non-hyperkeratotic, non-pigmented actinic keratoses of the face and scalp in immunocompetent patients when used in conjunction with lesion preparation in the physician's office when other therapies are considered medically less appropriate. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for METVIXIA (U.S. Patent No. 6,034,267) from PhotoCure ASA, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration and that FDA determine the product's regulatory review period. In a letter dated May 25, 2011, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of METVIXIA represented the first permitted commercial marketing or use of the product.

FDA has determined that the applicable regulatory review period for METVIXIA is 1,695 days. Of this time, 659 days occurred during the testing phase of the regulatory review period, while 1,036 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* December 8, 1999. The applicant claims February 24, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the testing phase began when an earlier IND became effective on December 8, 1999, which was 30 days after FDA receipt of the earlier IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* September 26, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for METVIXIA (NDA 21–415) was submitted on September 26, 2001.

3. *The date the application was approved:* July 27, 2004. FDA has verified the applicant's claim that NDA 21–415 was approved on July 27, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 871 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by August 22, 2011. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 19, 2011. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 25, 2011.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2011–15625 Filed 6–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage

for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301–496–7057; *fax:* 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

A System for Delivering Embolic Materials Endovascularly to Patients

Description of Technology: The Public Health Service seeks commercial entities interested in licensing patent rights that pertain to a system for delivering embolic materials endovascularly to patients. The system includes a smart catheter that provides quantitative feedback to a physician during embolotherapy. This includes a detecting portion for measuring flow velocity (*e.g.,* Doppler tip), amount of reflux, and amount of embolic particles (*e.g.,* embolization beads) delivered by the catheter. A graphical user interface displays the measured information in real-time.

Applications:

- Transarterial chemoembolization
- Drug eluting bead
- Intravenous drug delivery
- Drug distribution monitoring
- Real-time imaging

Inventors: Matthew Dreher, Elliot Levy, Karun Sharma, David Tabriz, Peter Guion, Ankur Kapoor, Bradford Wood (all NIHCC).

Patent Status: U.S. Provisional Application No. 61/486,722 filed 16 May 2011 (HHS Reference No. E–184–2011/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Michael A. Shmilovich, Esq.; 301–435–5019; shmilovm@mail.nih.gov.

Collaborative Research Opportunity: The NIH Clinical Center, Radiology and Imaging Sciences Department, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize a catheter for quantitative feedback during embolotherapy. Please contact Ken Rose, PhD at 301–435–3132 or *rosek@mail.nih.gov* for more information.

Liver Segmental Anatomy and Analysis From Vessel and Tumor Segmentation

Description of Technology: The invention is a novel graph-based method for the automated segmentation of tumors and major intra-hepatic blood vessels and identification of the liver anatomical segments. The method allows visualization and risk analysis for interventional planning involving the liver. The method avoids the shortcomings of the traditional graph cuts or intensity-based segmentation methods by including multi-phase enhancement modeling and shape likelihoods. The segmented vessels can be correctly classified into right, middle and left hepatic, and right and left portal veins using a hybrid process that incorporates anatomical information and competitive region growing. Tumors can be detected and segmented using their differential enhancement and shape with accuracy comparable to the reports from the Medical Image Computing and Computer Assisted Intervention (MICCAI) liver tumor segmentation competition. Furthermore, a vessel tracker allowed fitting planes to the major hepatic vasculature and identifying the liver segments according to the Couinaud atlas. The automated method can be used in conjunction with manual and automatic liver segmentations to perform enhanced visualization for diagnosis and planning of interventions.

Applications: To assist in the visualization, diagnosis and planning of interventional procedures involving the liver.

Advantages:

- The method avoids the shortcomings of the traditional segmentation methods by including multi-phase enhancement modeling and shape likelihoods.
- Tumors are segmented with accuracy comparable to the reports from MICCAI liver tumor segmentation competition.
- Liver segments according to the Couinaud Atlas are automatically identified.
- The automated method allows the enhanced visualization of the liver for diagnosis and planning of interventions.

Development Status: The algorithm and software of the method are fully developed.

Inventors: Marius G. Linguraru and Bradford J. Wood (NIHCC).

Patent Status: HHS Reference No. E–178–2011/0—Software/Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: A software package encompassing the method is available for licensing.

Licensing Contacts:

- Uri Reichman, PhD, MBA; 301–435–4616; *UR7a@nih.gov*
- Michael Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov*

Collaborative Research Opportunity: The NIH Clinical Center, Department of Radiology and Imaging Sciences, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize techniques for the enhanced visualization, diagnosis and image-based interventions of the liver. Please contact Ken Rose, PhD at 301–435–3132 or *rosek@mail.nih.gov* for more information.

MicroRNA–205 for the Treatment and Diagnosis of Parkinson Disease

Description of Technology: Parkinson disease (PD) is a devastating neurodegenerative movement disorder, pathologically characterized by selective loss of dopaminergic (DA) neurons in the substantia nigra pars compacta (SNpc) and the presence of intracytoplasmic inclusions named Lewy bodies and Lewy neurites (Schapira, *Baillieres Clin. Neurol.* 6:15–36, 1997). Increasing numbers of genes have been identified as a genetic cause of PD (Hardy *et al., Ann. Neurol.* 60:389–398, 2006), for example, multiple missense mutations in the leucine-rich repeat kinase 2 (LRRK2) gene were recently found to be associated with an autosomal dominant form of familial PD (Paisan-Ruiz *et al., Neuron* 44:595–600, 2004; Zimprich *et al., Neuron* 44:601–607, 2004; Zabetian et al., Neurology 65:741–744, 2005). Recent genome-wide association studies (GWAS) also revealed LRRK2, together with SNCA (encoding α-syn) and PARK16, as shared risk loci for PD (Simon-Sanchez *et al., Nat. Genet.* 41:1308–1312, 2009; Satake *et al., Nat. Genet.* 41:1303–1307, 2009), indicating a potential contribution of normal LRRK2 protein to the etiology of sporadic PD cases.

Micro-RNAs (miRNAs or miRs) are evolutionarily conserved small non-protein coding transcripts that bind to partially complementary binding sites in the 3' untranslated region (3'-UTR) of target messenger RNAs (mRNAs) and control the translation of their target mRNAs at the post-transcriptional level (Bartel, *Cell* 116:281–297, 2004). Several miRNAs have been associated with neurodegenerative disease as well as synaptic plasticity, memory formation and developmental cell fate decisions in the nervous system (Hebert and De Strooper, *Trends Neurosci.* 32:199–206, 2009; Kosik, *Nat. Rev. Neurosci.* 7:911–920, 2006).

NIH inventors have recently discovered that LRRK2 protein

expression is significantly increased in the brain of PD patients, while expression of miR–205 is specifically down-regulated in the same patients. Also, the NIH inventors have discovered that the expression levels of LRRK2 and miR–205 are dynamically regulated and reversely correlated in multiple brain regions and at different ages in mouse brains, indicating that miR–205 plays a regulatory role in LRRK2 protein expression.

Based on these novel findings, the present technology provides for novel methods of treatment of patients suffering from PD disease by modulating the amount of miR–205 in patients by administration of a miR–205 gene product, a vector encoding a miR–205 gene product or an agent that increases expression of miR–205. The present technology also provides for methods of determining the effectiveness of different candidate drugs for the treatment of PD, methods of diagnosing PD, or having an increased susceptibility to developing PD, and an *in vitro* process for identifying a therapeutic agent for the treatment of PD.

Applications: Therapeutics and diagnostics for PD.

Development Status: Early-stage.

Inventors: Huaibin Cai and Hyun J. Cho (NIA).

Patent Status: U.S. Provisional Application No. 61/430,626 filed 07 Jan 2011 (HHS Reference No. E–209–2010/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Suryanarayana Vepa, PhD, J.D.; 301–435–5020; *vepas@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute on Aging, Transgenics Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize microRNA–205 or other reagents for the treatment and diagnosis of Parkinson Disease. Please contact Nicole Guyton, PhD at 301–435–3101 or *darackn@mail.nih.gov* for more information.

Dated: June 14, 2011.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2011–15467 Filed 6–21–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of Federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

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Monoclonal Antibodies to Glypican-3 Protein and Heparin Sulfate for Treatment of Cancer

Description of Technology: Hepatocellular carcinoma (HCC) is the most common form of liver cancer, and is among the more deadly cancers in the world due to its late detection and poor prognosis. HCC is often associated with liver disease, curtailing traditional chemotherapy as a treatment option. While surgical resection offers the best method for long term treatment of the disease, only a small portion of HCC patients are eligible for this procedure. As a result, there is a need for new treatments that can be successfully applied to a large population of HCC patients.

Glypican-3 (GPC3) is a cell surface protein that is preferentially expressed on HCC cells. Evidence has demonstrated that a soluble form of GPC3 that is incapable of cell signaling has the ability to inhibit the growth of HCC cells. This suggested that blocking GPC3 signaling could serve as a therapeutic approach for treating HCC.

This invention concerns monoclonal antibodies against GPC3 and their use, either by themselves or as the targeting domain for an immunotoxin, for the treatment of GPC3-expressing cancers such as HCC. Specifically, the inventors have generated two distinct monoclonal antibodies to GPC3. The first monoclonal antibody (HN3) binds to a conformational epitope on the cell surface domain of GPC3. The second monoclonal antibody (HS20) binds specifically to heparin sulfate chains on GPC3.

By blocking GPC3 function, these antibodies can inhibit the growth of HCC cells, thereby decreasing the ability of tumors to grow and metastasize. Furthermore, by using the antibodies to target a toxin to only those cells that express GPC3, cancer cells can be eliminated while allowing healthy, essential cells to remain unharmed. Thus, monoclonal antibodies to GPC3 (and corresponding immunotoxins) represent a novel therapeutic candidate for treatment of HCC, as well as other cancers associated with the differential expression of GPC3.

Applications:

- Therapeutic candidates against cancers that overexpress GPC3;
- Antibodies for killing cancer cells by inhibiting GPC3-based cell signaling, thereby inhibiting tumor cell growth;
- Immunotoxins for killing cancer cells through the action of a toxic agent;
- Diagnostics for detecting cancers associated with GPC3 overexpression;
- Specific cancers include hepatocellular cancer (HCC), melanoma, thyroid cancer, lung squamous cell carcinoma, Wilms' tumor, neuroblastoma, hepatoblastoma, and testicular germ-cell tumors.

Advantages:

- Monoclonal antibodies create a level of specificity that can reduce deleterious side-effects;
- Multiple treatment strategies available including the killing of cancer cells with a toxic agent or by inhibiting cell signaling;
- Non-invasive and potentially non-liver toxic alternative to current HCC treatment strategies.

Development Status: Preclinical stage of development; cell culture data with HCC cells.

Inventors: Mitchell Ho (NCI) *et al.*

Patent Status: U.S. provisional application 61/477,020 (HHS technology reference E–130–2011/0–US–01).

For more information, see:

- M Feng *et al.* Recombinant soluble glypican 3 protein inhibits the growth of hepatocellular carcinoma *in vitro.* Int J Cancer 2011 May1;128(9):2246–2247, doi 10.1002/ijc.25549. [PMID: 20617511].
- SI Zitterman *et al.* Soluble glypican 3 inhibits the growth of hepatocellular

carcinoma *in vitro* and *in vivo.* Int J Cancer 2010 Mar 15;126(6):1291–1301. [PMID: 19816934].

Licensing Status: Available for licensing.

Licensing Contact: David A. Lambertson, PhD; 301–435–4632; *lambertsond@mail.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Laboratory of Molecular Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize human monoclonal antibodies or immunoconjugates such as immunotoxins and antibody-drug conjugates against GPC3, soluble GPC3 and its immunoconjugates such as Fc fusion proteins, large scale antibody production, and HCC xenograft mouse models. Please contact John Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Mouse Xenograft Model for Mesothelioma

Description of Technology: Malignant mesothelioma is a cancer that presents itself in the protective lining of several organs (*e.g.,* lung, heart, testis, etc.). The primary cause for mesothelioma is direct or indirect exposure to asbestos, although the disease can present without any prior exposure. Mesothelioma is relatively rare, but the prognosis for patients is poor, indicating a need to better understand and treat the disease. Current treatments often involve chemotherapy and radiation therapy, although recent studies have employed the use of therapeutic antibodies and antibody-targeted toxins.

This invention involves the creation of a new mouse model for mesothelioma. By creating xenografts with mesothelioma cells that express GFP-Luciferase fusion proteins, the xenografts can be detected to a high degree of sensitivity, and monitored for several months following implantation. The high level of detection sensitivity improves the ability to monitor disease progression in response to therapeutic candidates, thereby allowing more efficient drug screening and evaluation. This has already been demonstrated by using the mouse to evaluate an anti-mesothelioma immunotoxin known as SS1P, a drug candidate that is currently being evaluated for clinical effectiveness.

Applications:

- Animal model for screening compounds as potential therapeutics for mesothelioma;
- Animal model for studying the effectiveness of potential therapeutics for mesothelioma;
- Animal model for studying the pathology of mesothelioma.

Advantages:

- The model is created using well characterized, art-accepted mesothelioma cells;
- The model exhibits the classical clinical progression of mesothelioma, demonstrating its accuracy as a model;
- The use of GFP-Luciferase fusion proteins allow for non-invasive evaluation of mesothelioma progression and response to drug candidates;
- The use of GFP-Luciferase fusion proteins allow the use of highly sensitive detection systems such as bioluminescence.

Benefits:

- The convenient and efficient identification and evaluation of mesothelioma drug candidates.

Inventor: Mitchell Ho (NCI).

Patent Status: HHS Reference No. E–302–2009/0 — Research Tool. Patent protection is not being pursued for this technology.

For more information, see:

- M. Feng *et al.* In vivo imaging of human malignant mesothelioma grown orthotopically in the peritoneal cavity of nude mice. J Cancer. 2011 Mar 1;2:123–131. [PMID: 21479131];
- PCT Patent Application WO 2010/065044 (HHS technology reference E–336–2008/0–PCT–02);
- U.S. Patent 7,081,518 (HHS technology reference E–139–1999/0–US–07).

Licensing Status: The technology is available for non-exclusive licensing as a Biological material/Research tool.

Licensing Contact: David A. Lambertson, PhD; 301–435–4632; *lambertsond@mail.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Laboratory of Molecular Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize monoclonal antibodies and immunoconjugates targeting malignant mesotheliomas. Please contact John Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Increased Therapeutic Effectiveness of Immunotoxins Through the Use of Less Immunogenic Toxin Domains

Description of Technology: Targeted toxins (*e.g.,* immunotoxins) are therapeutics that have at least two important components: (1) A toxin domain that is capable of killing cells and (2) a targeting domain that is capable of selectively localizing the toxic domain to only those cells which should be killed. By selecting a targeting domain that binds only to certain diseased cells (*e.g.,* a cell which only expresses a cell surface receptor when in a diseased state), targeted toxins can kill the diseased cells while allowing healthy, essential cells to survive. As a result, patients receiving a targeted toxin are less likely to experience the deleterious side-effects associated with non-discriminate therapies such as chemotherapy or radiation therapy.

A particular toxin that has been used in targeted toxins is *Pseudomonas* exotoxin A (PE). The effectiveness of PE-containing targeted toxins has been demonstrated against various forms of cancer, including hairy cell leukemia (HCL) and pediatric acute lymphocytic leukemia (pALL). Although early variations these targeted toxins have demonstrated efficacy upon first administration, the continued administration of a targeted toxin often leads to a reduced patient response. The primary cause of the reduced response is the formation of neutralizing antibodies against PE by the patient.

Several variations of PE have been created to reduce the immunogenicity of PE as a means of increasing the therapeutic effectiveness of targeted toxins through multiple rounds of drug administration. This technology involves the identification of two important B-cell epitopes on PE, and the elimination of those epitopes by mutation. These new PE variants retain a sufficient cell killing activity while increasing their therapeutic effectiveness toward patients that receive multiple administrations. By further combining these new mutations with previously identified modifications that also improve the efficacy of PE-based targeted toxins, it may be possible to treat any disease characterized by cells that express a particular cell surface receptor when in a disease state.

Applications:

- Essential component of a targeted toxin, such as an immunotoxin (antibody-targeted toxin) or ligand-targeted toxin;
- Treatment of diseases that are associated with the increased expression of a cell surface receptor;
- Applicable to any disease associated with cells that preferentially express a specific cell surface receptor;
- Relevant diseases include various cancers, including lung, ovarian, breast, head and neck, and hematological cancers.

Advantages:

• Less immunogenic targeted toxin results in improved efficacy during multiple administrations;

• Targeted therapy decreases non-specific killing of healthy, essential cells, resulting in fewer side-effects and healthier patients.

Development Status: Preclinical stage of development.

Inventors: Pastan (NCI) *et al.*

Patent Status:

• U.S. provisional application 61/241,620 (HHS technology reference E–269–2009/0–US–01);

• PCT patent application PCT/US2010/048504 (HHS technology reference E–269–2009/0–PCT–02).

For more information, see:

• U.S. Patent Publication US 20100215656 A1 (HHS technology reference E–292–2007/0–US–06);

• U.S. Patent Publication US 20090142341 A1 (HHS technology reference E–262–2005/0–US–06);

• U.S. Patent 7,777,019 (HHS technology reference E–129–2001/0–US–07).

Licensing Status: Available for licensing.

Licensing Contact: David A. Lambertson, PhD; 301–435–4632; *lambertsond@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Molecular Biology Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: June 15, 2011.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2011–15492 Filed 6–21–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

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Mouse Model for Cerebral Cavernous Malformation, an Inherited Brain Disorder

Description of Technology: Cerebral Cavernous Malformation (CCM) is a brain disease affecting up to 0.5% of the worldwide population. CCM is characterized by grossly dilated vessels prone to leaking and hemorrhage which result in severe headaches, seizures, and strokes. Inherited forms of the disease are due to mutations in one of three loci, CCM1, CCM2, and CCM3. Prior efforts to develop mice with targeted null mutations in *Ccm1, Ccm2,* or *Ccm3* have been unsuccessful, as such mutations result in embryonic death.

The inventors have developed the first mouse model available for the study of CCM, in which mouse *Ccm2* can be conditionally deleted in blood-accessible and endothelial cells, resulting in neurological defects, ataxia, and brain hemorrhages consistent with the human disease. The model was generated through a cross of C57BL/6 *Ccm2*-floxed mice with C57BL/6 *MX–1–Cre* mice, which permits inducible ablation by polyinosinic:polycytidylic acid (pIpC).

Inventors: Ulrich Siebenlist (NIAID) and Yoh-suke Mukoyama (NHLBI).

Related Publications: In preparation.

Patent Status: HHS Reference No. E–158–2011/0—Research Material. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing under a Biological Materials License Agreement.

Licensing Contact: Tara L. Kirby, PhD; 301–435–4426; *tarak@mail.nih.gov.*

System to Increase Consistency and Reduce Variations in Contrast and Sensitivity in MRI Imaging

Description of Technology: The technology relates to the field of MRI. More specifically, the invention describes and claims system and methods related to the use of non-linear B_0 shims to improve excitation flip angle uniformity in high field MRI. The disclosed system and methods can be used in conjunction with existing multi-dimension excitation methods, including those that use parallel excitation to improve contrast and sensitivity in gradient echo magnetic resonance imaging. The technology is designed to overcome shortcomings associated with high field MRI, namely RF flip angle inhomogeneity due to wavelength effects that can lead to spatial variations in contrast and sensitivity.

Applications: High field MRI.

Advantages: The present system and methods will improve performance of high field MRI:

• Improve the transmit profile homogeneity, and therefore the uniformity of MRI images.

• The method is applicable to all MRI scanning with poor B1 uniformity. This includes situations when B1 variations are caused by the coil B1 profile, by the dielectric properties of the object (wavelength effects), or by a combination of both.

• The method is applicable with currently available single or multi-channel B1 coils.

Development Status:

• Proof of principle has been demonstrated on a prototype device.

• Demonstration of the application to human imaging is currently underway.

Inventors: Jeff Duyn (NINDS).

Relevant Publication: Duan Q, van Gelderen P, Duyn J. B_0 based shimming of RF flip angle in MRI. Submitted to Magnetic Resonance in Medicine.

Patent Status: U.S. Provisional Application No. 61/473,610 filed 08 Apr 2011 (HHS Reference No. E–129–2011/0–US–01).

Licensing Status: Available for licensing and commercial development.

Licensing Contacts:

• Uri Reichman, PhD, MBA; 301–435–4616; *UR7a@nih.gov.*

• John Stansberry, PhD; 301–435–5236; *js852e@nih.gov.*

Polyclonal Antibodies Against RGS7, a Regulator of G Protein Signaling, for Research and Diagnostic Use

Description of Technology: Investigators at the National Institutes of Health have generated a polyclonal antibody against the Regulator of G protein Signaling Protein 7 (RGS7). The RGS7 protein regulates neuronal G protein signaling pathways and inhibits signal transduction by increasing the GTPase activity of G protein alpha. RGS7 may play an important role in synaptic vesicle exocytosis and in the

rapid regulation of neuronal excitability and the cellular responses to stimulation. This polyclonal antibody was generated by using a purified fusion protein containing the regulator of guanine nucleotide-binding protein signaling (RGS) C-terminal region of bovine RGS. The antibody specifically recognizes RGS7 of mouse, rat, and human origin. The antibody is useful for studying the expression, functions, and interactions of RGS7 by Western blot and immunofluorescence analysis.

Applications:

• *Basic research tool for the study of RGS7.* Reagent for diagnostic applications such as Western Blotting, ELISA, immunofluorescence and immunohistochemistry in fixed tissue samples.

• *Reagent for biochemical techniques such as immunoprecipitation.* Development of diagnostics or therapeutics for diseases of the nervous system linked to RGS protein-regulated signaling including Parkinson's disease, schizophrenia, seizure disorders, multiple sclerosis, and opiate addiction.

Inventors: William F. Simonds and Jianhua Zhang (NIDDK).

Relevant Publications

1. Rojkova AM, Woodard GE, Huang TC, Combs CA, Zhang JH, Simonds WF. Ggamma subunit-selective G protein beta 5 mutant defines regulators of G protein signaling protein binding requirement for nuclear localization. J Biol Chem. 2003 Apr 4;278(14):12507–12512. [PMID: 12551930]

2. Nini L, Waheed AA, Panicker LM, Czapiga M, Zhang JH, Simonds WF. R7-binding protein targets the G protein beta 5/R7-regulator of G protein signaling complex to lipid rafts in neuronal cells and brain. BMC Biochem. 2007 Sep 19;8:18. [PMID: 17880698]

3. Panicker LM, Zhang JH, Posokhova E, Gastinger MJ, Martemyanov KA, Simonds WF. Nuclear localization of the G protein beta 5/R7-regulator of G protein signaling protein complex is dependent on R7 binding protein. J Neurochem. 2010 Jun;113(5):1101–1112. [PMID: 20100282]

Patent Status: HHS Reference No. E–077–2011/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: This technology is available as a research tool under a Biological Materials License.

Licensing Contact: Jaime Greene, M.S.; 301–435–5559; *greenejaime@mail.nih.gov.*

Collaborative Research Opportunity: The NIDDK Metabolic Diseases Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize polyclonal antibodies against the Regulator of G protein Signaling Protein 7 (RGS7). Please contact Anna Z. Amar at 301–451–2305 or *aa54d@nih.gov* for more information.

Oligonucleotide Compounds that Enhance Immunity to Cancer and Reduce Autoimmunity

Description of Technology: Suppressive cells, including macrophages and other myeloid-derived suppressor cells, regulatory T cells, and dendritic cells (DCs), have been attributed to tumor growth. DCs in particular are known to be associated with the induction of T cell tolerance in cancer, but molecular mechanisms that control DC dysfunction are complex and a better understanding of DC mechanisms in tumors is needed. Recently FOXO3, originally identified as a tumor suppressor, was associated with DC dysfunction. Additionally, therapeutics targeting FOXO3 are known to be effective at killing many tumors types, synergize with traditional therapies, and show efficacy against tumors that are otherwise resistant to conventional treatments.

The researchers at the NIH have demonstrated for the first time that FOXO3 expression by DC coincides with expression of suppressive genes that negatively regulate T cell function. They have also demonstrated that silencing FOXO3 simultaneously changes DC function, eliminating tolerogenicity and enhancing their immunostimulatory capacity. Specifically, the inventors have developed siRNAs or oligonucleotides that enhance an immune response and neutralize the activity of FOXO3 in DCs by converting suppressive cells into immunostimulatory cells. This novel approach could be applied to cancer vaccines, where dendritic cells could be treated with these small molecules prior to use in clinical therapies. Alternatively, small molecules that stimulate FOXO3 expression could be used for inducing immune suppression for autoimmune diseases like type I diabetes or multiple sclerosis.

Applications

• An adjuvant to neutralize FOXO3 and elicit a more potent response to cancer immune-based therapies, either at the time of vaccination or during an on-going anti-tumor immune response.

• Suppressing an immune response through the induction of FOXO3 expression to prevent tissue-specific autoimmune diseases like type I Diabetes or Multiple sclerosis, where known target antigens have been identified.

Advantages

• The ability to treat multiple tumor types linked to FOXO3 expression.

• siRNAs can be delivered to different organs with minimal cytotoxicity.

• Through the modulation of FOXO3 gene expression, therapeutics for both cancer and autoimmune diseases can be developed.

Development Status: Pre-clinical proof of principle.

Inventors: Arthur A. Hurwitz (NCI) *et al.*

Publication: Watkins SK, Zhu Z, Riboldi E, Shafer-Weaver KA, Stagliano KE, Sklavos MM, Ambs S, Yagita H, Hurwitz AA. FOXO3 programs tumor-associated DCs to become tolerogenic in human and murine prostate cancer. J Clin Invest. 2011 Apr 1;121(4):1361–1372. [PubMed: 21436588]

Patent Status

• U.S. Provisional Application No. 61/293,098 filed January 7, 2010 (HHS Reference No. E–086–2010/0–US–01).

• PCT Application No. PCT/US2011/020315 filed January 6, 2011 (HHS Reference No. E–086–2010/0–PCT–02).

Licensing Status: Available for licensing.

Licensing Contact: Whitney Hastings; 301–451–7337; *hastingw@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute Cancer and Inflammation Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize agents that both block FOXO3 function and enforce FOXO3 expression. Please contact John Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: June 14, 2011.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2011–15477 Filed 6–21–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Sickle Cell and CKD Ancillary Studies.

Date: July 18, 2011.

Time: 10 to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Robert Wellner, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 706, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–4721, *rw175w@nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Pediatric Endocrinologist K12 Programs.

Date: July 18, 2011.

Time: 1 to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Robert Wellner, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, ROOM 706, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–4721, *rw175w@nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Feasibility Studies for Clinical Trials in Type 1 Diabetes.

Date: July 18, 2011.

Time: 12 to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Michele L. Barnard, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Recruitment Determinants Ancillary Studies.

Date: July 28, 2011.

Time: 1 to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Michele L. Barnard, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 16, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–15637 Filed 6–21–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Molecular Genetics.

Date: July 6, 2011.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Richard A Currie, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1108, MSC 7890, Bethesda, MD 20892, (301) 435–1219, *currieri@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Cell Biology.

Date: July 12–13, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Elena Smirnova, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301–435–1236, *smirnove@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR 11–081: Shared instrumentation: X-ray facilities.

Date: July 14–15, 2011.

Time: 8:30 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Arnold Revzin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7806, Bethesda, MD 20892, (301) 435–1153, *revzina@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, RFA–OD–11–001: Lasker Clinical Research Scholars Program (SI2).

Date: July 18, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Syed M Quadri, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6210, MSC 7804, Bethesda, MD 20892, 301–435–1211, *quadris@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Shared Instrumentation: Flow Cytometry.

Date: July 26–27, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: David Balasundaram, PhD, Scientific Review Offcer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840,Bethesda, MD 20892, 301–435–1022, *balasundaramd@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Shared Instrumentation: Mass Spectrometers.

Date: July 27–28, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: Nuria E Assa-Munt, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Statistical Genetics.

Date: July 28, 2011.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Michael K Schmidt, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2214, MSC 7890, Bethesda, MD 20892, (301) 435–1147, *mschmidt@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Endocrinology and Metabolism.

Date: July 28, 2011.

Time: 10:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817, (Virtual Meeting).

Contact Person: Krish Krishnan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, (301) 435–1041, *krishnak@csr.nih.gov.*

(Catalog of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 15, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–15489 Filed 6–21–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Institutional Postdoctoral Training Programs.

Date: July 15, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Brian R. Pike, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892, 301–594–3907, *pikbr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: June 16, 2011.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–15635 Filed 6–21–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel.

Date: July 27–28, 2011.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health/NCRR/OR, Democracy 1, 6701 Democracy Blvd., 1064, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Guo Zhang, PhD, MD, Scientific Review Administrator, National Center for Research Resources, or National Institutes of Health, 6701 Democracy Boulevard, 1 Democracy Plaza, Room 1064, MSC 4874, Bethesda, MD 20892–4874, 301–435–0812, *zhanggu@mail.nih.gov.*

Name of Committee: National Center for Research Resources Special Emphasis Panel; Research Centers in Minority Institutions (RCMI).

Date: August 2, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Blvd., Bethesda, MD 20817.

Contact Person: Steven Birken, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, 1 Democracy Plaza, Room 1078, 6701 Democracy Blvd., Bethesda, MD 20892, 301–435–0815, *birkens@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333; 93.702, ARRA Related Construction Awards, National Institutes of Health, HHS)

Dated: June 16, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–15634 Filed 6–21–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License; The Development of Ulipristal Acetate for the Treatment of Symptomatic Uterine Fibroids

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant to PregLem SA of an exclusive patent license to practice the inventions embodied in US Patent Application 12/021,610 entitled, ''Method for Treating Uterine Fibroids'' [HHS Ref. E–057–2008/0–US–01], and all continuing applications and foreign counterparts. The patent rights in this invention have been assigned to the Government of the United States of America and to Laboratoire HRA Pharma. The exclusive license contemplated in this notice is solely to the patent rights assigned to the

Government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to:

The use of ulipristal acetate for the treatment of symptomatic uterine fibroids.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before July 22, 2011 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Patrick P. McCue, PhD, Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5560; Facsimile: (301) 402–0220; E-mail: *mccuepat@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: This invention concerns methods for the treatment of symptomatic uterine fibroids using a selective progesterone receptor modulator compound, ulipristal acetate (a.k.a. CDB–2914). Ulipristal acetate reversibly binds the progesterone receptor with high affinity and little or no anti-glucocorticoid activity. Proposed clinical indications for ulipristal acetate include emergency/daily contraception, treatment of uterine fibroids, endometriosis, dysfunctional uterine bleeding, and cancer.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7 within thirty (30) days from the date of this published notice.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: June 15, 2011.

Richard U. Rodriguez,

Director, Division of Technology Development & Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2011–15486 Filed 6–21–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License; Devices for Clearing Mucus From Endotracheal Tubes

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a worldwide exclusive license, to practice the invention embodied in: HHS Ref. No. E–074–2005/0 ''Mucus Slurping Endotracheal Tube''; U.S. Patent 7,503,328 to Oculus Innovative Sciences, Inc., a company incorporated under the laws of the State of California having its headquarters in Petaluma, California. The United States of America is the assignee of the rights of the above inventions. The contemplated exclusive license may be granted in a field of use limited to devices for clearing mucus from endotracheal tubes.

DATES: Only written comments and/or applications for a license received by the NIH Office of Technology Transfer on or before July 22, 2011 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael A. Shmilovich, Esq., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5019; Facsimile: (301) 402–0220; E-mail: *shmilovm@mail.nih.gov*. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: The patent intended for licensure covers a mucus slurping device used to remove mucus before it reaches the tip of the endotracheal tube (ETT). A continuous aspiration endotracheal tube for subglottic secretions is fitted at its distal-most tip with a molded, hollow, concentric plastic ring with 3–4 (or more) small (less than l mm in diameter) suction ports, the latter positioned in the most dependent part of the ETT. A suction line is extended to the tip of the ETT and suction was activated for approximately half of a second, synchronized to the early part of expiration; and repeated once a minute, or as desired. Studies involving intubated sheep showed that all mucus was cleared from test animal and that mucus samples collected showed no infections that typically put patients at risk for ventilator associated pneumonia.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: June 14, 2011.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2011–15480 Filed 6–21–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) Drug Testing Advisory Board (DTAB) on July 12 and 13, 2011. The DTAB will convene in both open and closed sessions over these two days.

On July 13 from 10 a.m. to 12:30 p.m. E.D.T., the meeting will be open to the public to review public responses to SAMHSA's Request for Information on oral fluid as a potential alternative specimen under the Mandatory Guidelines for Federal Workplace Drug Testing Programs. In addition, the

DTAB will deliberate and vote on proposed recommendations.

The public is invited to attend the open session in person or to listen via teleconference. Due to the limited seating space and call-in capacity, registration is requested. Public comments are welcome. To register, make arrangements to attend, obtain the teleconference call-in numbers and access codes, submit written or brief oral comments, or to request special accommodations for persons with disabilities, please register at the SAMHSA Advisory Committees' Web site at *http://nac.samhsa.gov/Registration/meetingsRegistration.aspx* or by contacting the CSAP DTAB Designated Federal Official, Dr. Janine Denis Cook (see contact information below).

On July 12 between 9 a.m.–4 p.m. E.D.T. and July 13 between 2 p.m. and 4 p.m. E.D.T., the Board will meet in closed session to discuss proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. This portion of the meeting is closed as determined by the Administrator, SAMHSA, in accordance with 5 U.S.C. 552b(c)(9)(B) and 5 U.S.C. App. 2, Section 10(d).

Substantive program information, a summary of the meeting, and a roster of DTAB members may be obtained as soon as possible after the meeting, either by accessing the SAMHSA Advisory Committees' Web site, *http://www.nac.samhsa.gov/DTAB/meetings.aspx,* or by contacting Dr. Cook. The transcript for the open meeting will also be available on the SAMHSA Committee Web site within three weeks after the meeting.

Committee Name: Substance Abuse and Mental Health Services, Administration's Center for Substance Abuse Prevention Drug Testing, Advisory Board.

DATES/time/type: July 12, 2011 from 9 a.m. to 4 p.m. E.D.T.: CLOSED. July 13, 2011 from 10 a.m. to 12:30 p.m. E.D.T.: OPEN. July 13, 2011 from 2 p.m. to 4 p.m. E.D.T.: CLOSED.

Place: SAMHSA Office Building, Sugarloaf Conference Room, 1 Choke Cherry Road, Rockville, Maryland 20857.

Contact: Janine Denis Cook, PhD, Designated Federal Official, SAMHSA Drug Testing Advisory Board, 1 Choke Cherry Road, Room 2–1045, Rockville, Maryland 20857. *Telephone:* 240–276–2600, *Fax:* 240–276–2610, *E-mail: janine.cook@samhsa.hhs.gov.*

Dated: June 15, 2011.

Carol Rest-Mincberg,

Acting Division Director, Division of Workplace Programs, Center for Substance Abuse Prevention, Substance Abuse and Mental Health, Services Administration.

[FR Doc. 2011–15374 Filed 6–21–11; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–1991–DR; Docket ID FEMA–2011–0001]

Illinois; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Illinois (FEMA–1991–DR), dated June 7, 2011, and related determinations.

DATES: *Effective Date:* June 10, 2011.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Illinois is hereby amended to include the Public Assistance program for the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 7, 2011.

Alexander, Franklin, Gallatin, Hardin, Jackson, Lawrence, Massac, Perry, Pope, Pulaski, Randolph, Saline, White, and Williamson Counties for Public Assistance (already designated for Individual Assistance).

Hamilton, Jefferson, Marion, Union, Wabash, Washington, and Wayne Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–15624 Filed 6–21–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–1984–DR; Docket ID FEMA–2011–0001]

South Dakota; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of South Dakota (FEMA–1984–DR), dated May 13, 2011, and related determinations.

DATES: *Effective Date:* June 8, 2011.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of South Dakota is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 13, 2011.

Union County for Public Assistance (already designated for emergency protective measures [Category B], limited to direct Federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–15527 Filed 6–21–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–1984–DR; Docket ID FEMA–2011–0001]

South Dakota; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of South Dakota (FEMA–1984–DR), dated May 13, 2011, and related determinations.

DATES: *Effective Date:* June 10, 2011.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of South Dakota is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 13, 2011.

Yankton County for Public Assistance (already designated for emergency protective measures [Category B], limited to direct Federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–15528 Filed 6–21–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–1985–DR; Docket ID FEMA–2011–0001]

Oklahoma; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Oklahoma (FEMA–1985–DR), dated May 13, 2011, and related determinations.

DATES: *Effective Date:* May 13, 2011.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated May 13, 2011, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Oklahoma resulting from a severe winter storm and snowstorm during the period of January 31 to February 5, 2011, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Oklahoma.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance, including direct Federal assistance, in the designated areas and Hazard Mitigation throughout the State. You are further authorized to provide emergency protective measures, including snow assistance, under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period. You may extend the period of assistance, as warranted. This assistance excludes regular time costs for the sub-grantees' regular employees. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, William J. Doran III, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Oklahoma, have been designated as adversely affected by this major disaster:

Craig, Creek, Jefferson, Logan, Mayes, Nowata, Okmulgee, Osage, Ottawa, Pawnee, Pottawatomie, Rogers, Stephens, Tulsa, Wagoner, and Washington Counties for Public Assistance, including direct Federal assistance.

Craig, Creek, Jefferson, Logan, Mayes, Nowata, Okmulgee, Osage, Ottawa, Pawnee, Pottawatomie, Stephens, Wagoner, and Washington Counties for emergency protective measures (Category B), including snow assistance, under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period. The assistance for Rogers and Tulsa Counties will be provided for a period of 72 hours.

All counties within the State of Oklahoma are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–15522 Filed 6–21–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Extension of Agency Information Collection Activity Under OMB Review: Security Threat Assessment for Individuals Applying for a Hazardous Materials Endorsement for a Commercial Drivers License

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-day Notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0027, abstracted below to OMB for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on August 30, 2011, 75 FR 52962. The collection involves applicant submission of biometric and biographic information for TSA's security threat assessment in order to obtain the hazardous materials endorsement (HME) on a commercial drivers license (CDL) issued by the States and the District of Columbia.

DATES: Send your comments by July 22, 2011. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Joanna Johnson, TSA PRA Officer, Office of Information Technology (OIT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–3651; e-mail *TSAPRA@dhs.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at *http://www.reginfo.gov.* Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies' estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Security Threat Assessment for Individuals Applying for a Hazardous Materials Endorsement for a Commercial Drivers License.

Type of Request: Revision of a currently approved collection.

OMB Control Number: 1652–0027.

Forms(s): N/A.

Affected Public: Drivers seeking a hazardous material endorsement (HME) on their commercial driver's license (CDL).

Abstract: This collection supports the implementation of sec. 1012 of the USA PATRIOT Act (Pub. L. 107–56, 115 Stat. 272, 396, Oct. 26, 2001), which mandates that no State or the District of Columbia may issue a HME on a CDL unless TSA has first determined the driver is not a threat to transportation security. TSA's regulations at 49 CFR part 1572 describe the procedures, standards, and eligibility criteria for security threat assessments on individuals seeking to obtain, renew, or transfer a HME on a CDL. In order to conduct the security threat assessment, States (or a TSA designated agent in States that elect to have TSA perform the collection of information) must collect information in addition to that already collected for the purpose of HME applications, which will occur once approximately every five years. The driver is required to submit an application that includes personal biographic information (for instance, height, weight, eye and hair color, date of birth); information concerning legal status, mental health defects history, and criminal history; and fingerprints. In addition, 49 CFR part 1572 requires States to maintain a copy of the driver application for a period of one year. TSA proposes to amend the application to collect minor additional information, such as legal status document information and whether the driver is a new applicant or renewing or transferring the HME. This will enable the program to better understand and forecast driver retention, transfer rate, and drop-rate, thus improving customer service, reducing program costs, and providing comparability with other Federal background checks, including the Transportation Workers Identification Credential (TWIC).

Number of Respondents: 300,000.

Estimated Annual Burden Hours: An estimated 978,000 hours annually.

Issued in Arlington, Virginia, on June 15, 2011.

Joanna Johnson,

TSA Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2011–15529 Filed 6–21–11; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities; Form N–300; Extension of an Existing Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review; Form N–300, Application to File Declaration of Intention; OMB Control No. 1615–0078.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on March 28, 2011 at 76 FR 17144, allowing for a 60-day public comment period. USCIS received one comment in connection with that notice, which requested an extension of this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until July 22, 2011. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this

notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Management and Budget (OMB) USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Products Division, Office of the Executive Secretariat, Clearance Office, 20 Massachusetts Avenue, Washington, DC 20529–2020. Comments may also be submitted to DHS via facsimile to 202–272–0997 or via e-mail at *uscisfrcomment@dhs.gov,* and to the OMB USCIS Desk Officer via facsimile at 202–395–5806 or via e-mail at *oira_submission@omb.eop.gov.* Please do not submit requests for individual case status inquiries to these addresses. If you are seeking information about the status of your individual case, please check ''My Case Status'' online at *https://egov.uscis.gov/cris/Dashboard,* or call the USCIS National Customer Service Center at 1–800–375–5283 (TTY 1–800–767–1833).

When submitting comments by e-mail please make sure to add OMB Control Number 1615–0078 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* Application to File Declaration of Intention.

(3) Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection: Form N–300; U.S. Citizenship and Immigration Services (USCIS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form N–300 will be used by permanent residents to file a declaration of intention to become a citizen of the United States. This collection is also used to satisfy documentary requirements for those seeking to work in certain occupations or professions, or to obtain various licenses.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 45 responses at .75 hours (45 minutes) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 34 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: *http://www.regulations.gov/.*

We may also be contacted at: USCIS, Regulatory Products Division, Office of the Executive Secretariat, 20 Massachusetts Avenue, NW., Washington, DC 20529–2020, Telephone number 202–272–8377.

Dated: June 15, 2011.

Sunday Aigbe,

Chief, Regulatory Products Division, Office of the Executive Secretariat, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2011–15511 Filed 6–21–11; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

Agency Information Collection Activities; Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection for Review; Form I–333, Obligor Change of Address; OMB Control No. 1653–0042.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (ICE), will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on April 14, 2011 Vol. 76 No. 72, p. 20966, allowing for a 60 day public comment period. ICE received no comments during this 60 day period.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted for thirty days until July 22, 2011.

Written comments and suggestions from the public and affected agencies regarding items contained in this notice and especially with regard to the estimated public burden and associated response time should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to OMB Desk Officer, for United States Immigration and Customs Enforcement, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved Information Collection.

(2) *Title of the Form/Collection:* Obligor Change of Address.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–333. U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. The information collected on the Form I–333 is necessary for U.S.

Immigration and Customs Enforcement (ICE) to provide immigration bond obligors a standardized method to notify ICE of address updates. Upon receipt of the formatted information records will then be updated to ensure accurate service of correspondence between ICE and the obligor.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 12,000 responses at 15 minutes (.25 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 3,000 annual burden hours.

Requests for a copy of the proposed information collection instrument, with instructions; or inquiries for additional information should be directed to: Office of the Chief Financial Officer/OAA/Records Branch, U.S. Immigration and Customs Enforcement, 500 12th Street, SW., STOP 5705, Washington, DC 20536–5705.

Dated: June 16, 2011.

John Ramsay,

Forms Program Manager, Office of Asset Administration, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. 2011–15531 Filed 6–21–11; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

Agency Information Collection Activities; Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection for Review; Form I–901, Fee Remittance for Certain F, J and M Non-immigrants; OMB Control No. 1653–0034.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (ICE), has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on April 14, 2011, Vol. 763 No. 72, p. 20966, allowing for a 60 day comment period. No comments were received on this information collection during this 60 day period.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted for thirty days until July 22, 2011.

Written comments and suggestions from the public and affected agencies regarding items contained in this notice and especially with regard to the estimated public burden and associated response time should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to OMB Desk Officer, for United States Immigration and Customs Enforcement, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of currently approved information collection.

(2) *Title of the Form/Collection:* Fee Remittance for Certain F, J and M Nonimmigrants.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–901, U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individual or Households. Public Law 104–208, Subtitle D, Section 641 directs the Attorney General, in consultation with the Secretary of State and the Secretary of Education, to develop and conduct a program to collect information on nonimmigrant foreign students and exchange visitors from approved institutions of higher education, as defined in section 101(a) of the Higher Education Act of 1965, as amended or in a program of study at any other DHS-approved academic or language-training institution, to include approved private elementary and secondary schools and public secondary schools, and from approved exchange visitor program sponsors designated by the Department of State (DOS). It also authorized a fee, not to exceed $100, to be collected from these students and exchange visitors to support this information collection program. DHS has implemented the Student and Exchange Visitor Information System (SEVIS) to carry out this statutory requirement.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 600,000 responses at 19 minutes (.32 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 192,000 annual burden hours.

Requests for a copy of the proposed information collection instrument, with instructions; or inquiries for additional information should be directed to: Office of the Chief Financial Officer/OAA/Records Branch, U.S. Immigration and Customs Enforcement, 500 12th Street, SW., STOP 5705, Washington, DC 20536–5705.

Dated: June 16, 2011.

John Ramsay,

Forms Program Manager, Office of Asset Administration, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. 2011–15533 Filed 6–21–11; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

Agency Information Collection Activities; Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection for Review; Form G–146, Nonimmigrant Checkout Letter; OMB Control No. 1653–0020.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (ICE), will be submitting the following information collection request for review and clearance in

accordance with the Paperwork Reduction Act of 1995. The Information Collection was previously published in the **Federal Register** on April 14, 2011 Vol. 76 No. 72, p. 20998, allowing for a 60-day public comment period. ICE received no comments on this Information Collection from the public during this 60-day period.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted for thirty days July 22, 2011.

Written comments and suggestions from the public and affected agencies regarding items contained in this notice and especially with regard to the estimated public burden and associated response time should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for U.S. Immigration and Customs Enforcement, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved Information Collection.

(2) *Title of the Form/Collection:* Non-Immigrant Checkout Letter.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form G–146, U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individual or Households. When an alien (other than one who is required to depart under safeguards) is granted the privilege of voluntary departure without the issuance of an Order to Show Cause, a control card is prepared. If, after a certain period of time, a verification of departure is not received, actions are taken to locate the alien or ascertain his or her whereabouts. Form G–146 is used to inquire of persons in the United States or abroad regarding the whereabouts of the alien.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 20,000 responses at 10 minutes (.16 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 3,220 annual burden hours.

Requests for a copy of the proposed information collection instrument, with instructions; or inquiries for additional information should be directed to: Office of the Chief Financial Officer/OAA/Records Branch, U.S. Immigration and Customs Enforcement, 500 12th Street, SW., STOP 5705, Washington, DC 20536–5705.

Dated: June 16, 2011.

John Ramsay,

Forms Program Manager, Office of Asset Administration, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. 2011–15532 Filed 6–21–11; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

Agency Information Collection Activities: New Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection for Review; Suspicious/Criminal Activity Tip Reporting; OMB Control No. 1653–NEW.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (ICE), will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on April 14, 2011 Vol. 76, No. 72 p. 20997 allowing for a 60 day public comment period. No comments were received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted for thirty days until July 22, 2011.

Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for United States Immigration and Customs Enforcement, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* New information collection.

(2) *Title of the Form/Collection:* Suspicious/Criminal Activity Tip Reporting.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. DHS/ICE is implementing multiple tools for tip reporting to allow the public and law enforcement partners to report tip information regarding crimes within the jurisdiction of DHS.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

Number of respondents	Form name/form number	Avg. burden per response (in hours)
66,000	Homeland Security Investigations Tip Form	0.16
20	Bulk Cash Smuggling Center Contact Form	0.16
118,000	Suspicious Activity Tip Line	0.10

(6) *An estimate of the total public burden (in hours) associated with the collection:* 22,363 annual burden hours.

Requests for a copy of the proposed information collection instrument, with instructions; or inquiries for additional information should be directed to: Office of the Chief Financial Officer/OAA/Records Branch, U.S. Immigration and Customs Enforcement, 500 12th Street SW., STOP 5705 Washington, DC 20536–5705.

Dated: June 16, 2011.

John Ramsay,

Forms Program Manager, Office of Asset Administration, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. 2011–15530 Filed 6–21–11; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5480–N–53]

Notice of Submission of Proposed Information Collection to OMB; HOPE VI Application

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

The information is required to allow HUD to obligate grant funds in accordance with the HOPE VI program authorizing statute, and to manage the grants that are awarded.

DATES: *Comments Due Date: July 22, 2011.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2577–0208) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; e-mail *OIRA–Submission@omb.eop.gov* fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Colette Pollard at *Colette.Pollard@hud.gov;* or telephone (202) 402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the Information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: HOPE VI Application.

OMB Approval Number: 2577–0208.

Form Numbers: HUD 52774, HUD 52780, HUD 52785, HUD 2994–A, HUD 52797, HUD 52790, HUD 52825–A, HUD–2880, HUD 52800, HUD 52861, HUD 96010, HUD 96011, HUD 52799, HUD 52787, SF–424, HUD 52680–A, HUD 52861, HUD 53001–a, SFLLL, HUD–52798.

Description of the Need for the Information and its Proposed Use: The information is required to allow HUD to obligate grant funds in accordance with the HOPE VI program authorizing statute, and to manage the grants that are awarded.

Frequency of Submission: On occasion, Quarterly, Semi-annually. Annually.

	Number of respondents	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden	286	4.811		19.270		26,516

Total Estimated Burden Hours: 26,516.

Status: Revision of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: June 16, 2011.

Colette Pollard,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2011–15519 Filed 6–21–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5480–N–56]

Notice of Submission of Proposed Information Collection to OMB; Public Housing Financial Management Template

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

The Public Housing Assessment System requires public housing agencies to submit financial information annually to HUD. The Uniform Financial Reporting Standards for HUD housing programs requires that this information be submitted electronically, using generally accepted accounting principles, in a prescribed format. The Operating Fund Program regulation (24 CFR 990) requires PHAs to submit information at a project level.

DATES: *Comments Due Date: July 22, 2011.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2535–0107) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; e-mail: *OIRA-Submission@omb.eop.gov* fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Colette Pollard at *Colette.Pollard@hud.gov;* or telephone: (202) 402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the Information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: Public Housing Financial Management Template.

OMB Approval Number: 2535–0107.

Form Numbers: None.

Description of the Need for the Information and its Proposed Use

The Public Housing Assessment System requires public housing agencies to submit financial information annually to HUD. The Uniform Financial Reporting Standards for HUD housing programs requires that this information be submitted electronically, using generally accepted accounting principles, in a prescribed format. The Operating Fund Program regulation (24 CFR 990) requires PHAs to submit information at a project level.

Frequency of Submission: Annually.

	Number of respondents	×	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden	4,106		1.890		5.490		42,620

Total Estimated Burden Hours: 42,620.

Status: Extension of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: June 16, 2011.

Colette Pollard,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2011–15513 Filed 6–21–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5480–N–54]

Notice of Submission of Proposed Information Collection to OMB; Public Housing Inventory Removal Application

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

This collection of information centralizes and standardizes HUD's review and approval of non-funded, noncompetitive requests of Public Housing Authorities (PHAs) to remove public housing property from their inventories via disposition, demolition, voluntary conversion, required conversion, home ownership, or eminent domain proceedings.

DATES: *Comments Due Date:* July 22, 2011.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2577–0075) and should be sent to: HUD Desk Officer,

Office of Management and Budget, New Executive Office Building, Washington, DC 20503; e-mail *OIRA-Submission@omb.eop.gov*; fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Colette Pollard at *Colette.Pollard@hud.gov;* or telephone (202) 402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the Information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: Public Housing Inventory Removal Application.

OMB Approval Number: 2577–0075.

Form Numbers: HUD–52860–C, HUD–52860–F, HUD–52860–B, HUD–52860–D, HUD–52860–E, and HUD–52860.

Description of the Need for the Information and its Proposed Use: This collection of information centralizes and standardizes HUD's review and approval of non-funded, noncompetitive requests of Public Housing Authorities (PHAs) to remove public housing property from their inventories via disposition, demolition, voluntary conversion, required conversion, home ownership, or eminent domain proceedings.

Frequency of Submission: On occasion.

	Number of respondents	×	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden	851		1		7,062		6,010

Total Estimated Burden Hours: 6,010.

Status: Extension without change of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: June 16, 2011.

Colette Pollard,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2011–15516 Filed 6–21–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5480–N–55]

Notice of Submission of Proposed Information Collection to OMB ''Logic Model'' Grant Performance Report Standard

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

Applicants of HUD Federal Financial Assistance are required to indicate intended results and impacts. Grant recipients report against their baseline performance standards. This process standardizes grants progress reporting requirements and promotes greater emphasis on performance and results in grant programs.

DATES: *Comments Due Date: July 22, 2011.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2535–0114) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; e-mail *OIRA–Submission@omb.eop.gov* fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Colette Pollard at *Colette.Pollard@hud.gov;* or telephone (202) 402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the Information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: ''Logic Model'' Grant Performance Report Standard.

OMB Approval Number: 2535–0114.

Form Numbers: HUD 96010, each program utilizing the Logic Model will have the same form number and the Program Name following the number to associate the logic model to the specific program.

Description of the need for the information and its proposed use: Applicants of HUD Federal Financial Assistance are required to indicate intended results and impacts. Grant recipients report against their baseline performance standards. This process standardizes grants progress reporting requirements and promotes greater emphasis on performance and results in grant programs.

Frequency of submission: Quarterly, Annually.

	Number of respondents	×	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden	11,000		2.2		4.511		109,175

Total estimated burden hours: 109,175.

Status: Reinstatement with change of a previously approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: June 16, 2011.

Colette Pollard,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2011–15514 Filed 6–21–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5521–D–01]

Delegation of Authority for the Office of Departmental Equal Employment Opportunity

AGENCY: Office of the Secretary, HUD.

ACTION: Notice of delegation of authority.

SUMMARY: In this notice, the Secretary of HUD delegates concurrent authority to the Director and Deputy Director, Office of Departmental Equal Employment Opportunity (ODEEO) with respect to all matters pertaining to the work of ODEEO and supersedes any prior delegation of authority from the Secretary to the Director, ODEEO.

DATES: *Effective Date:* June 14, 2011.

FOR FURTHER INFORMATION CONTACT: Michelle A. Cottom, Acting Director, Office of Departmental Equal Employment Opportunity, Department of Housing and Urban Development, Room 2134, 451 7th Street, SW., Washington, DC 20410–6000, telephone number 202–402–5627. (This is not a toll-free number.) Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: For HUD, a commitment to equal opportunity is fundamental, not only relative to the public's expectations of fair housing without discrimination, but also to HUD's employment of a workforce that reflects the communities it serves. HUD remains committed to building a leading equal employment opportunity (EEO) program. Section 1614.102 of title 29, Code of Federal Regulations requires that the agency's EEO program be organized and structured to maintain a workplace that is free from discrimination in any of the agency's policies, procedures, or practices. It also provides that the EEO program support the agency's strategic mission and that the ODEEO Director be under the direct supervision of the agency head. The ODEEO Director, Deputy Director, and other ODEEO professional staff that are responsible for EEO programs must have regular and effective means of informing the agency head and senior management officials of the status of EEO programs and must be involved in, and consulted on, management/personnel actions.

Section A. Authority Delegated

The Secretary hereby delegates to the Director and Deputy Director, ODEEO concurrent authority and responsibility to promulgate and implement all policies, procedures, and practices to operate a model EEO program. The Secretary may revoke the authority authorized herein, in whole or part, at any time.

Section B. Authority Excepted

The authority delegated in this document does not include the authority to sue or be sued or to issue or waive regulations.

Section C. Authority To Redelegate

The authority delegated in this document may be redelegated.

Section D. Authority Superseded

This delegation supersedes any previous delegations of authority from the Secretary to the Director, ODEEO.

Authority: Section 7(d) of the United States Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: June 14, 2011.

Shaun Donovan,

Secretary .

[FR Doc. 2011–15512 Filed 6–21–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[FR–5415–FA–08]

Announcement of Funding Awards; Indian Community Development Block Grant Program; Fiscal Year 2010

AGENCY: Office of Native American Programs, Office of Public and Indian Housing, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with Section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in a competition for funding under the Fiscal Year 2010 (FY 2010) Notice of Funding Availability (NOFA) for the Indian Community Development Block Grant (ICDBG) Program. This announcement contains the consolidated names and addresses of this year's award recipients under the ICDBG.

FOR FURTHER INFORMATION CONTACT: For questions concerning the ICDBG Program awards, contact the Area Office of Native American Programs (ONAP) serving your area or Deborah M. Lalancette, Office of Native Programs, 1670 Broadway, 23rd Floor, Denver, CO 80202, telephone (303) 675–1600. Hearing or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: This program provides grants to Indian Tribes and Alaska Native Villages to develop viable Indian and Alaska Native communities, including the creation of decent housing, suitable living environments, and economic opportunities primarily for persons with low and moderate incomes as defined in 24 CFR 1003.4.

The FY 2010 awards announced in this Notice were selected for funding in a competition posted on HUD's Web site on August 24, 2010. Applications were scored and selected for funding based on the selection criteria in that notice and Area ONAP geographic jurisdictional competitions.

The amount appropriated in FY 2010 to fund competitive ICDBG applications was $61,040,000. The allocations for the Area ONAP geographic jurisdictions are as follows:

Eastern/Woodlands	$7,073,351
Southern Plains	13,094,889
Northern Plains	8,694,184
Southwest	22,737,279
Northwest	3,105,735
Alaska	6,334,562
Total	$61,040,000

In accordance with Section 102 (a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat.1987, 42 U.S.C. 3545), the Department is publishing the names, addresses, and amounts of the 88 awards made under the various regional competitions in Appendix A to this document.

Dated: June 14, 2011.

Sandra B. Henriquez,

Assistant Secretary for Public and Indian Housing.

Appendix A

INDIAN COMMUNITY DEVELOPMENT BLOCK GRANT PROGRAM FISCAL YEAR 2010 AWARD RECIPIENTS

Name/address of applicant	Amount funded	Activity funded	Project description
All Mission Indian Housing Authority (La Jolla), Debra Skallerud, Operations Manager, 27740 Jefferson Ave, Ste 260, Temecula, CA 92590.	$605,000	Public Facility Infrastructure	Construction of infrastructure on 72 acre home development site.
All Mission Indian Housing Authority (Torres-Martinez), Debra Skallerud, Operations Manager, 27740 Jefferson Ave, Ste 260, Temecula, CA 92590.	605,000	Housing Construction	Construct 5 homes.
Bear River Band of Rohnerville Rancheria, Honorable Leonard Bowman, Tribal Chairperson, 27 Bear River Drive, Loleta, CA 95551.	605,000	Housing Construction	Construct 3 homes.
Big Pine Paiute Tribe of the Owens Valley, Honorable Virgil Moose, Tribal Chairperson, P.O. Box 700, Big Pine, CA 93513.	605,000	Housing Rehabilitation	Rehab 15 homes.
Bishop Paiute Tribe, Glenn Hall, CEO, 50 TU SU Lane, Bishop, CA 93514.	605,000	Public Facility	Elders Center Rehabilitation.
Cheesh-Na Tribe, Lorraine Radigan, Chief Financial Officer, P.O. Box 241, Gakona, AK 99586.	600,000	Public Facility Community Center.	Clinic & multi-use facility.
Chemehuevi Indian Tribe, Honorable Charles Wood, Chairman, P.O. Box 1976, Havasu Lake, CA 92363.	605,000	Public Facility Infrastructure	Water tank replacement and system changes.
Cherokee Nation of Oklahoma, Honorable Chad Smith, Principal Chief, P.O. Box 948, Tahlequah, OK 74465.	726,765	Public Facility Community Center and Microenterprise.	Collinsville food distribution and Microenterprise Program.
Cheyenne-Arapaho Tribes of Oklahoma, Honorable Janice Boswell, Governor, P.O. Box 38, Concho, OK 73022.	799,380	Public Facility Special Needs	Head Start Childcare Center.
Chickasaw Nation, Honorable Bill Anoatubby, Governor, P.O. Box 1548, Ada, OK 74821.	800,000	Public Facility Community Center.	Chickasaw Nation Connerville Senior-Community Center.
Choctaw Nation of Oklahoma, Honorable Gregory E. Pyle, Chief, P.O. Drawer 1210, Durant, OK 74702.	800,000	Public Facility	Construction of a Fire and Emergency Response Complex in Idabel, Oklahoma.
Citizen Potawatomi Nation, Honorable John A. Barrett, Chairman, 1601 S. Gordon Cooper Drive, Shawnee, OK 74801.	800,000	Economic Development	Construction of 2 Grocery Stores.
Cocopah Indian Tribe, Honorable Sherry Cordova, Chairperson, County 15 and Avenue G, Somerton, AZ 85350.	571,002	Housing Rehabilitation	Rehab 10 homes.
Coeur d'Alene Tribal Housing Authority, Rosanna Allen, Executive Director, P O Box 267, Plummer, ID 83851.	500,000	Housing Rehabilitation	Rehabilitation of 35 low-rent homes.
Confederated Tribes of Grand Ronde, Honorable Cheryle A. Kennedy, Chairwoman, 9615 Grand Ronde Road, Grande Ronde, OR 97347.	500,000	Public Facility Special Purpose.	Develop a 3,000 sq. ft. transition center for women.
Crow Creek Housing Authority, Joseph Sazue, Jr. Executive Director, P.O. Box 19, Fort Thompson, SD 57339.	900,000	Housing Rehabilitation	Rehabilitation of 34 units.
Curyung Tribal Council, Honorable Thomas Tilden, 1st Chief, P.O. Box 216, Dillingham, AK 99576.	600,000	Housing Construction	Construct four homes.
Delaware Tribe of Oklahoma, Honorable Paula Pechonick, Chief, 170 NE Barbara Avenue, Bartlesville, OK 74006.	800,000	Public Facility Community Center.	Social Services Building.
Eastern Band of Cherokee Indians of NC, Honorable Michell Hicks, Principal Chief, P.O. Box 455, Cherokee, NC 28719.	600,000	Public Facility Community Center.	Snowbird Youth Center.
Eastern Shawnee Tribe of Oklahoma, Honorable Glenna J. Wallace, Chief, P.O. Box 350, Seneca, MO 64865.	800,000	Public Facility	Public Safety Building.
Elko Band of Te-Moak Tribe, Honorable Gerald Temoke, Chairman, 1745 Silver Eagle Drive, Elko, NV 89801.	516,934	Public Facility Center	Construct an Education Center.
Hannahville Indian Community, Kenneth Meshigaud, Chairperson, N14911 Hannahville B1 Rd., Wilson, MI 49896.	600,000	Economic Development	Expansion Convenience Store-Gas Station.
Ho-Chunk Nation, Honorable Wilfrid Cleveland, President, W9814 Airport Rd., Black River Falls, WI 54615.	600,000	Public Facility Community Center.	Dells Dam Community Center.
Hualapai Indian Tribe, Honorable Wilfred Whatoname, Sr. Chairman, P.O. Box 179, Peach Springs, AZ 86434.	825,000	Public Facility	10 Unit Elder Group Home.

INDIAN COMMUNITY DEVELOPMENT BLOCK GRANT PROGRAM FISCAL YEAR 2010 AWARD RECIPIENTS—Continued

Name/address of applicant	Amount funded	Activity funded	Project description
Jamestown S'Klallam Tribe, Honorable William Ron Allen, CEO/Tribal Chairman, 1033 Old Blyn Highway, Sequim, WA 98382.	442,341	Public Facilities Infrastructure	Tribal water system expansion.
Jicarilla Apache Housing Authority, Lisa Manwell, Executive Director, P.O. Box 486, Dulce, NM 87528.	825,000	Housing Rehabilitation	Rehabilitation of 13 homes.
Kaibab Band of Paiute Indians, Honorable Manual Savala, Chairman, HC 65, Box 2, Fredonia, AZ 86022.	605,000	Economic Development	RV Park.
Karuk Tribe, Phil Albers, Jr., Vice Chairman, P.O. Box 1016, Happy Camp, CA 96039.	595,000	Public Facility Center	Health and Wellness Center.
Keweenaw Bay Indian Community, Honorable Warren C. Swartz, Jr., President, 16429 Beartown Rd, Baraga, MI 49908.	600,000	Public Facility Infrastructure	Brewery-Vuk-Dynamite Hill water line.
Kickapoo Tribe of Oklahoma, Honorable Gilbert Salazar, Chairman, P.O. Box 70, McLoud, OK 74851.	799,780	Public Facility Special Needs	Assisted Living Units.
Knik Tribal Council, Richard Porter, Executive Director, P.O. Box 871565, Wasilla, AK 99687.	247,062	Housing Rehabilitation	Housing rehabilitation and weatherization.
Lac du Flambeau Band of Lake Superior, Dee Mayo, Tribal Vice-Chairperson, P.O. Box 67, Lac du Flambeau, WI 54538.	600,000	Public Facility Community Center.	Community Facility Youth Center.
Leech Lake Band of the MN Chippewa Tribe, Honorable Arthur LaRose, Chairman, 6530 U.S. Hwy 2, Cass Lake, MN 56633.	600,000	Public Facility Community Center.	Sugar Point Community Center.
Little River Band of Ottawa Indians, Honorable Larry Romanelli, Ogema, 375 River Street, Manistee, MI 49660.	477,275	Public Facility Community Center.	Family Services/Health Center.
Los Coyotes Band of Cahuilla Indians, Honorable Francine Kupsch, Tribal Spokeswoman, P.O. Box 189, Warner Springs, CA 92086.	600,200	Housing Construction	Construction of 4 homes.
Lower Brule Sioux Tribe, Honorable Michael Jandreau, Tribal Chairman, 187 Oyate Circle, Lower Brule, SD 57548.	523,677	Housing Construction	Construction of 2 homes and 1–2 bedrooms duplex.
Lummi Nation Housing Authority, Honorable Jacqueline Ballew, Chairperson, 2828 Kwina Road, Bellingham, WA 98226.	500,000	Public Facilities Infrastructure	Infrastructure development for low-income housing.
Mechoopda Tribe of Chico Rancheria, Ryan Heath Browning, Executive Director, 125 Mission Ranch Boulevard, Chico, CA 95926.	595,000	Housing Acquisition	Acquire 2 homes.
Mescalero Housing Authority, Alvin Benally, Executive Director, P.O. Box 227, Mescalero, NM 88340.	70,443	Housing Rehabilitation	Rehabilitation of 2 homes.
Muscogee (Creek) Nation, Honorable A.D. Ellis, Principal Chief, P.O. Box 580, Okmulgee, OK 74447.	800,000	Public Facility Infrastructure	Infrastructure Project for Student Housing.
Native Village of Cantwell, Honorable Veronica Nicolas, President, P.O. Box 94, Cantwell, AK 99729.	600,000	Housing Construction	Construct a Tri-plex.
Native Village of Deering, Honorable Michael Jones, President, P.O. Box 89, Deering, AK 99736.	600,000	Housing Rehabilitation	Housing rehabilitation and weatherization.
Native Village of Kobuk, Honorable Edward Gooden Jr., President, P.O. Box 871565, Kobuk, AK 99751.	600,000	Housing Rehabilitation	Housing rehabilitation and weatherization.
Native Village of Selawik, Honorable Clyde Ramoth Sr., President, P.O. Box 39, Selawik, AK 99770.	500,000	Housing Rehabilitation	Water and sewer services to eight homes.
Native Village of Shungnak, Honorable Glenn Douglas, President, P.O. Box 64, Shungnak, AK 99773.	600,000	Housing Construction	Construct five homes.
Native Village of Tazlina, Honorable Johnny Goodlataw, President, P.O. Box 87, Glenallen, AK 99588.	600,000	Housing Construction	Construct three single family homes.
Navajo Nation, Honorable Joe Shirley, Jr., President, P.O. Box 7440, Window Rock, AZ 86515.	3,722,554	Public Facility Infrastructure	Power lines and water treatment facility.
Nelson Lagoon, Dan Duame, Executive Director, Aleutian Housing Authority, P.O. Box 13–NLG, Cold Bay, AK 99571.	187,500	Housing Rehabilitation	Housing rehabilitation for two single family homes.
Northern Arapaho Housing Authority, Patrick Goggles, Executive Director, 501 Ethete Road, Ethete, WY 82520.	470,507	Public Facility Infrastructure	Construction of a natural gas pipeline to serve low-income housing residents.
Northern Cheyenne Tribal Housing Authority, Lafe Haugen, Executive Director, P.O. Box 327, Lame Deer, MT 59043.	900,000	Housing Rehabilitation	Rehabilitation of 31 homes.
Northern Ponca Housing Authority, Robert Waite, Acting Executive Director, 1501 Michigan Ave., Norfolk, NE 68701.	1,100,000	Housing Rehabilitation	Rehabilitation of 150 homes.
Northern Pueblos Housing Authority (Picuris), Terry Hudson, Executive Director, 11 West Gutierrez, Suite 10, Santa Fe, NM 87506.	432,302	Housing Rehabilitation	Rehabilitation of 10 homes.

INDIAN COMMUNITY DEVELOPMENT BLOCK GRANT PROGRAM FISCAL YEAR 2010 AWARD RECIPIENTS—Continued

Name/address of applicant	Amount funded	Activity funded	Project description
Northern Pueblos Housing Authority (San Ildefonso), Terry Hudson, Executive Director, 11 West Gutierrez, Suite 10, Santa Fe, NM 87506.	605,000	Housing Rehabilitation	Rehabilitation of 13 homes.
Northern Pueblos Housing Authority (Tesuque), Terry Hudson, Executive Director, 11 West Gutierrez, Suite 10, Santa Fe, NM 87506.	605,000	Housing Rehabilitation	Rehabilitation of 13 homes.
Northwestern Band of the Shoshone Nation Housing Authority, Jon Warner, Executive Director, 707 N. Main Street, Brigham City, UT 84302.	600,000	Public Facility Community Center and Housing Construction.	Construction of 6 homes, Construction of a 2,000 sq ft education building.
Nottawaseppi Huron Band of the Potawatomi, Honorable Homer Mandoka, Chairperson, 2221 1½ Mile Rd., Fulton, MI 49052.	598,500	Public Facility Community Center.	Health Center Expansion.
Oglala Sioux (Lakota) Housing Authority, Paul Iron Cloud, Chief Executive Officer, 400 East Main, Pine Ridge, SD 57770.	1,100,000	Housing Rehabilitation	Rehabilitation of 120 homes, to include mold remediation.
Ohkay Owingeh Housing Authority, Tomasita Duran, Executive Director, P.O. Box 1059, Ohkay Owingeh, NM 87566.	605,000	Housing Rehabilitation	Rehab 10 homes.
Ottawa Tribe of Oklahoma, Honorable John R. Ballard, Chief, P.O. Box 110, Miami, OK 74355.	800,000	Housing Rehabilitation	Housing Rehabilitation.
Pascua Yaqui Tribe, Honorable Peter Yucupicio, Chairman, 7474 South Camino de Oeste, Tucson, AZ 85757.	2,200,000	Public Facility	Education Complex.
Pawnee Nation of Oklahoma, Honorable George Howell, President, P.O. Box 470, Pawnee, OK 74058.	800,000	Public Facility	Law Enforcement Center.
Pokagon Band of Potawatomi Indians, Honorable Matthew Wesaw, Chairperson, P.O. Box 180, Dowagiac, MI 49047.	600,000	Public Facility Community Center.	Pokagon Cultural Center Project.
Ponca Tribe of Oklahoma, Honorable Douglas G. Rhodd, Sr., Chairman, 20 White Eagle Drive, Ponca City, OK 74601.	800,000	Housing Rehabilitation	Housing Rehabilitation.
Port Gamble S'Klallam Tribe, Honorable Jeromy Sullivan, Tribal Chairperson, 31912 Little Boston Road N.E., Kingston, WA 98346.	500,000	Public Facility Community Center.	Construct a 5,100 sq. ft. preschool building.
Pribilof Island Aleut Community of St. Paul Island, Elaine Baker, Grant Writer, P.O. Box 86, St. Paul, AK 99660.	600,000	Housing Rehabilitation	Install ampy meter and water system upgrades.
Pueblo de Cochiti Housing Authority, Mary Jo Trujillo, Secretary Board of Commissioners, P.O. Box 98, Cochiti Pueblo, NM 87072.	605,000	Housing Rehabilitation & Construction.	Rehabilitation of 15 homes and construction of 2 homes.
Quapaw Tribe of Oklahoma, Honorable John Berrey, Chairman, P.O. Box 765, Quapaw, OK 74363.	799,999	Economic Development	Convenience Store.
Quechan Tribally Designated Housing Entity, Robert Letendre, Tenent Relations Officer, 1860 West Sapphire Lane, Winterhaven, CA 92283.	825,000	Public Facility Infrastructure	Streets, Roads & Sidewalks.
Reno-Sparks Indian Colony, Honorable Arlan Melendez, Tribal Chairman, 98 Colony Road, Reno, NV 89502.	548,745	Housing Rehabilitation	Rehabilitation of 38 homes with water damage.
Rosebud Sioux Tribe, Honorable Rodney Bordeaux, Tribal Chairman, P.O. Box 430, Rosebud, SD 57570.	1,100,000	Public Facility Community Center.	Construction of 4 multi-purpose, community centers.
Salish and Kootenai Housing Authority, Jason Adams, Executive Director, P.O. Box 38, Pablo, MT 59855.	1,100,000	Housing Rehabilitation and Homebuyer Assistance.	Rehabilitation of 19 homes, homebuyer assistance, counseling and closing costs and down payment assistance.
San Felipe Pueblo Housing Authority, Issac Perez, Executive Director, P.O. Box 4222, San Felipe, NM 87001.	825,000	Housing Rehabilitation	Rehabilitation of 15 homes.
Santa Rosa Band of Cahuilla Indians, Rebecca Rose Tortes, Grant Consultant, P.O. Box 609, Hemet, CA 92546.	580,500	Housing Construction	Construct 5 homes.
Sault Ste. Marie Tribe of Chippewa Indians of MI, Honorable Darwin "Joe" McCoy, Chairperson, 523 Ashmun Street, Sault Ste. Marie, MI 49783.	597,576	Housing Rehabilitation	Kincheloe Rehabilitation.
Seneca-Cayuga Tribe of Oklahoma, Honorable Leroy Howard, Chief, 23701 S. 655 Road, Grove, OK 74344.	799,965	Public Facility Special Needs	AOA Elder Nutrition Center.
Squaxin Island Tribe, Honorable David Lopeman, Tribal Chairman, 10 S. E. Squaxin Lane, Shelton, WA 98584.	499,968	Public Facility Infrastructure	Design, engineering, and infrastructure for development of a community center.
St. Regis Band of Mohawk Indians of NY, Honorable Mark Garrow, Chief, 412 State Route 57, Akwesasne, NY 13655.	600,000.	Public Facility Community Center.	Diabetes Center.
Sitka Tribe of Alaska, Lisa Gassman, General Manager, 456 Katlin Street, Sitka, AK 99835.	600,000	Public Facility	Baranof Island Housing Authority maintenance facility.
Suquamish Tribe, Honorable Leonard Forsman, Tribal Chairman, P.O. Box 498, Suquamish, WA 98371.	163,426	Public Facility Infrastructure	Infrastructure development for low-income housing.

INDIAN COMMUNITY DEVELOPMENT BLOCK GRANT PROGRAM FISCAL YEAR 2010 AWARD RECIPIENTS—Continued

Name/address of applicant	Amount funded	Activity funded	Project description
Tamaya Housing Incorporated, Cordelia Guerrero, Executive Director, 51 Jemez Canyon Dam Road Ste. 201–F, Santa Ana Pueblo, NM 87004.	605,000	Housing Construction	Construct 4 homes.
Tonkawa Tribe of Oklahoma, Honorable Donald L. Patterson, President, 1 Rush Buffalo Road, Tonkawa, OK 74653.	800,000	Public Facility Infrastructure	Infrastructure Water-Sewer.
United Keetoowah Band of Cherokee Indians, Honorable George Wickliffe, Chief, P.O. Box 746, Tahlequah, OK 74465.	800,000	Public Facility Community Center.	Training Center.
Utah Paiute Housing Authority, Jessie Laggis, Executive Director, 665 North, 100 East, Cedar City, UT 84720.	900,000	Housing Rehabilitation	Rehabilitation of 24 units.
Washoe Tribe of Nevada and California, Debby Carlson, Grants Manager, 919 Hwy 395 South, Gardnerville, NV 89410.	535,000	Public Facility Center	Wellness Center.
Wells Indian Colony Band of Te-Moak Tribe, Honorable Paula Salazar, Chairwoman, P.O. Box 809, Wells, NV 89835.	605,000	Public Facility Center	Multi Purpose Community Center Phase II.
White Earth Band of the MN Chippewa Tribe, Honorable Erma Vizenor, Chairperson, P.O. Box 418, White Earth, MN 56591.	600,000	Public Facility Community Center.	Health Building.
Wyandotte Nation, Honorable Leaford Bearskin, Chief, 64700 E. Highway 60, Wyandotte, OK 74370.	369,000	Housing Rehabilitation	Housing Rehabilitation.
Yerington Paiute Tribe, Lee Shaw, Development Coordinator, 171 Campbell Lane, Yerington, NV 89447.	605,000	Public Facility Center	Construct a Community Center.

[FR Doc. 2011–15508 Filed 6–21–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R6–R–2010–N194; 60138–1265–6CCP–S3]

Bowdoin National Wildlife Refuge Complex, Malta, MT; Comprehensive Conservation Plan

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce that our draft comprehensive conservation plan (CCP) and environmental assessment (EA) for Bowdoin National Wildlife Refuge Complex is available. This draft CCP/EA describes how the Service intends to manage this refuge complex for the next 15 years.

DATES: To ensure consideration, we must receive your written comments on the draft CCP/EA by July 25, 2011. Submit comments by one of the methods under **ADDRESSES**.

ADDRESSES: Send your comments or requests for more information by any of the following methods.

E-mail: bowdoin@fws.gov. Include ''Bowdoin NWR Complex'' in the subject line of the message.

Fax: Attn: Laura King, Planning Team Leader, 406–644–2661.

U.S. Mail: Laura King, Planning Team Leader, c/o National Bison Range, 58355 Bison Range Road, Moiese, MT 59824.

Information Request: A copy of the CCP/EA may be obtained by writing to U.S. Fish and Wildlife Service, Division of Refuge Planning, 134 Union Boulevard, Suite 300, Lakewood, Colorado 80228; or by download from *http://mountain-prairie.fws.gov/planning.*

FOR FURTHER INFORMATION CONTACT: Laura King, 406–644–2211, ext. 210 (phone); 406–644–2661 (fax); or *laura_king@fws.gov* (e-mail); or David C. Lucas, 303–236–4366 (phone): 303–236–4792 (fax): or *david_c_lucas@fws.gov.*

SUPPLEMENTARY INFORMATION: The 85,713-acre Bowdoin National Wildlife Refuge Complex (refuge complex) is part of the National Wildlife Refuge System. It is located in the mixed-grass prairie region of north-central Montana, within an area known as the prairie pothole region. The refuge complex oversees management of five national wildlife refuges: Bowdoin National Wildlife Refuge and four unstaffed satellite refuges—Black Coulee, Creedman Coulee, Hewitt Lake, and Lake Thibadeau National Wildlife Refuges. In addition, the refuge complex also manages the four-county Bowdoin Wetland Management District (district), which has nine waterfowl production areas in Blaine, Hill, Phillips, and Valley Counties along with conservation easements that protect approximately 40,159 acres of wetlands and grasslands. While the five national wildlife refuges and the wetland management district were established under different authorities, the primary purpose is to provide migration, nesting, resting, and feeding habitat for migratory birds in their wetlands and uplands. Bowdoin National Wildlife Refuge has been designated as an important bird area through a program administered by the National Audubon Society. The four satellite refuges have both fee title and private lands within their boundaries. These lands are encumbered by refuge and flowage easements giving the Service the right to impound water, control the uses that occur on that water, and control any hunting and trapping. Access to these privately owned areas is by landowner permission only.

The refuge complex provides opportunities for the public to enjoy compatible wildlife-dependent public use activities including hunting, limited fishing, wildlife observation, photography, environmental education, and interpretation. A full-time staff of five employees and various summer temporaries manage and study the refuge habitats and maintain visitor facilities. Domestic livestock grazing, prescribed fire, and haying are the primary management tools used to maintain and enhance upland habitats. Water level manipulation is used to improve wetland habitats. Invasive and

nonnative plant species are controlled and eradicated. Large, intact, native prairie communities can still be found throughout the refuge complex providing nesting habitat for over 29 species of resident and migratory birds. Native grazers such as pronghorn, white-tailed deer, and mule deer browse and graze the uplands. Four wetland classes are found on the refuge complex: Temporary, seasonal, semipermanent, and permanent and include both freshwater and saline wetlands. There are more than 10,000 acres of wetlands in the refuge complex. These wetlands have a diverse distribution of sizes, types, locations, and associations. The chemistry of surface waters in these wetlands tends to be dynamic because of interactions among numerous factors, such as the position of the wetland in relation to ground water flow systems, chemical composition of ground water, surrounding land uses, and climate. As part of the central flyway, this concentration of wetlands attracts thousands of migrating shorebirds and waterfowl to the refuge complex.

Approximately 25,000 people visit the refuge annually. A 15-mile interpreted auto tour route and nature trail on the Bowdoin National Wildlife Refuge account for the majority of visitor use. Fishing is only open on McNeil Slough and Beaver Creek WPAs. The remaining complex waters do not support a sport fishery due to high salinity levels or shallow water depth. Excluding Holm WPA, the remaining complex is open to limited hunting of waterfowl and upland game birds. The four satellite refuges (with landowner permission) and the remaining eight WPAs are also open to big game hunting, according to state regulations and seasons.

This draft CCP/EA includes the analyses of three different sets of alternatives including three alternatives for managing the refuge complex, two alternatives to evaluate the divestiture of Lake Thibadeau, and five alternatives for addressing the salinity and blowing salts issue on Bowdoin National Wildlife Refuge.

Alternatives for the Overall Management of the Refuge Complex

Alternative A, Current Management (No Action). Funding, staff levels, and management activities at the refuge complex would not change. The current staff of five Service employees would continue to manage Bowdoin National Wildlife Refuge Complex primarily for migratory birds. The Service would continue to manipulate native grasslands using various management techniques including prescribed fire, haying, and grazing. Approximately 10 percent of the uplands would be grazed annually, and there would be minimal monitoring of response. As resources become available, cropland on waterfowl production areas would be restored to native grasses and forbs; however, dense nesting cover would continue to be seeded on highly erodible lands in the wetland management district. The Service would continue to use mechanical and chemical methods to control existing and new infestations of Russian olive. Larger infestations of invasive species such as crested wheatgrass would continue to be given little to no attention due to the extent of infestation and the lack of resources and staff.

The Service would continue to attempt to mimic natural conditions on managed wetlands to meet the needs of migratory waterbirds. The 19 ground water wells on and around Bowdoin Refuge would be monitored to collect water quality data for the refuge and the Beaver Creek Waterfowl Production Area. Lake Bowdoin and Dry Lake would continue to be managed as closed basins. Visitor services programs including hunting, fishing, wildlife observation, photography, environmental education, and interpretation would remain at current levels.

Alternative B, the Proposed Action. The Service would conserve natural resources by restoring, protecting, and enhancing native mixed-grass prairie and maintaining high-quality wetland habitat for target migratory and resident birds within the Bowdoin National Wildlife Refuge Complex. Invasive and nonnative plants that are causing habitat losses and fragmentation would be controlled or eradicated. Research would be conducted to control crested wheatgrass and restore treated areas. Enhanced wetlands would be managed to mimic natural conditions for wetland-dependent migratory birds during spring and fall migrations and during the breeding and nesting season.

Visitor services programs would be enhanced, providing additional opportunities for staff- and volunteer-led programs to provide a greater understanding of the purposes of the refuge complex, importance of conserving migratory birds and the unique mixed-grass prairie and wetlands, and an awareness of the mission of the U.S. Fish and Wildlife Service and the National Wildlife Refuge System. A sanctuary area would be created for waterfowl on the east 60 percent of the Bowdoin National Wildlife Refuge during the hunting season, closing this to all foot traffic. A new wildlife observation site would be added on the auto tour route. The Service would investigate the need and consequences of offering a big game hunt at Bowdoin Refuge. The success of these additional efforts and programs would depend on added staff, research, and monitoring programs, including additional operations funding, infrastructure, and new and expanded partnerships.

Alternative C. This alternative includes most of the elements in Alternative B. In addition, the Service would increase the water management infrastructure (for example, water delivery systems, dikes, and levees to manipulate individual wetlands) to create a more diverse and productive wetland complex. Biological staff would monitor the level of sedimentation occurring in natural wetlands and plan for its removal to restore the biological integrity of these wetlands. Through partnerships, the Service would increase the acres of invasive species treated annually with an emphasis on preventing further encroachment of crested wheatgrass and Russian olive trees into native grassland. The Service would investigate the feasibility of offering a limited, archery-only, big game hunt at Bowdoin Refuge. The refuge complex would serve as a conservation learning center for the area. Public access would be improved to Creedman Coulee Refuge.

Alternatives for Lake Thibadeau National Wildlife Refuge

Using a divestiture model, developed by the Mountain-Prairie Region of the Service, the habitat quality and ability of Lake Thibadeau National Wildlife Refuge to meet its purposes and support the goals of the National Wildlife Refuge System, were evaluated. The Service owns less than 1 percent of the lands within the 3,868-acre approved acquisition boundary; the remaining area is private lands encumbered by refuge and flowage easements. These easements give the Service the right to manage the impoundments and the uses that occur on that water and to control hunting and trapping, but these easements do not prohibit development, grazing, or agricultural uses. Due to upstream development in the watershed, the impoundments do not receive adequate water supplies and are often dry enough to be farmed; the surrounding upland areas are also farmed or heavily grazed. This loss or lack of habitat has resulted in the Service's proposed action to divest this refuge. The Service completed an environmental analysis of two alternatives to address the situation at the Lake Thibadeau Refuge:

(1) Lake Thibadeau Refuge Alternative 1—Current management (no action);

(2) Lake Thibadeau Refuge Alternative 2—Divestiture (proposed action).

Alternatives for Salinity and Blowing Salts on Bowdoin National Wildlife Refuge

The principle sources of water for the Bowdoin National Wildlife Refuge are precipitation, floodwater from Beaver Creek, ground-water seepage, water deliveries from the Milk River Project, and irrigation return flows. The last three sources of water add dissolved solids (salinity) to the refuge waters, particularly Lake Bowdoin, a closed basin. In addition, the refuge and adjoining lands are underlain by glacial till and shale containing high concentrations of soluble salts. The Milk River Project water rights for Bowdoin refuge are limited and insufficient to improve wetland water quality. As water evaporates from Lake Bowdoin, salts have become concentrated and water salinity has increased. Historically, two methods have been used to improve Lake Bowdoin's water quality and reduce salinity levels: (1) Discharges of saline water into Beaver Creek; and (2) managing Dry Lake as an evaporation basin for Lake Bowdoin's water. Neither of these methods is acceptable due to impacts from windblown salts and saline water discharge. As a consequence, evaporation has continued to increase salinity levels in Lake Bowdoin to levels that will eventually negatively impact the diversity of aquatic vegetation and invertebrates. Waterfowl production will also be negatively affected, particularly if more suitable freshwater areas are not available or significantly reduced during the breeding season.

The Service hopes to address the salinity and blowing salts issue by developing a water management system on Bowdoin National Wildlife Refuge Complex that would protect the environment and mitigate current and future salt-dust-blowing concerns for neighboring properties, while providing quality water and wildlife habitat for migratory birds. A benchmark for achieving this goal would be to meet the Service's salinity objective of sustaining a brackish water quality level of approximately 7,000 mg/L of total dissolved solids (salts) in Lake Bowdoin. The Service developed and analyzed five alternatives to address the salinity and blowing salts issue for Lake Bowdoin in the Bowdoin National Wildlife Refuge including (1) current management (no action), (2) Evaporation ponds and removal of salt residue, (3) Flushing by Beaver Creek, (4) Underground injection and flushing by Beaver Creek (proposed action), and (5) Pumping to the Milk River. The Service has identified salinity and blowing salts alternative 4 as the best option (proposed action) for addressing this issue based on the effectiveness of treatment, environmental and social consequences, and cost.

Public Availability of Comments

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time.

The environmental review of this project will be conducted in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*); NEPA Regulations (40 CFR parts 1500–1508); other appropriate Federal laws and regulations; Executive Order 12996; the National Wildlife Refuge System Improvement Act of 1997; and Service policies and procedures for compliance with those laws and regulations.

Dated: August 25, 2010.

Hugh Morrison,

Acting Regional Director.

[FR Doc. 2011–15551 Filed 6–21–11; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAK–963000–L1410000–FQ0000; AA–5964, AA–3060, AA–5934]

Public Land Order No. 7770; Extension of Public Land Order No. 6884; Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order extends the duration of the withdrawal created by Public Land Order No. 6884, for an additional 20-year period. The extension is necessary to continue to protect the recreational values of the United States Forest Service's Kenai River Recreation Area, the Russian River Campground Area, and the Lower Russian Lake Recreation Area.

DATES: *Effective Date:* October 2, 2011.

FOR FURTHER INFORMATION CONTACT: Robert L. Lloyd, Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513; 907–271–4682. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The purpose for which the withdrawal was first made requires this extension in order to continue to protect the recreational values of the Kenai River Recreation Area, the Russian River Campground Area, and the Lower Russian Lake Recreation Area. The withdrawal extended by this order will expire on October 1, 2031, unless as a result of a review conducted prior to the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f), the Secretary of the Interior determines that the withdrawal shall be further extended. It has been determined that this action is not expected to have any significant effect on subsistence uses and needs pursuant to Section 810 of the Alaska National Interest Lands Conservation Act, 16 U.S.C. 3120.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, it is ordered as follows:

Public Land Order No. 6884 (56 FR 49847 (1991)), as corrected (56 FR 56275, (1991)) which withdrew approximately 1,855 acres of National Forest System land from settlement, sale, location, or entry under the general land laws, including the United States mining laws (30 U.S.C. ch 2), but not from leasing under the mineral leasing laws, to protect recreational values of the Kenai River Recreation Area, the Russian River Campground Area, and the Lower Russian Lake Recreation Area, is hereby extended for an additional 20-year period until October 1, 2031.

Authority: 43 CFR 2310.4.

Dated: June 7, 2011.

Wilma A. Lewis,

Assistant Secretary—Land and Minerals Management.

[FR Doc. 2011–15484 Filed 6–21–11; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAK–963000–L1410000–FQ0000; AA–3060]

Public Land Order No. 7769; Extension of Public Land Order No. 6888, Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order extends the withdrawal created by Public Land Order No. 6888, for an additional 20-year period. The extension is necessary to continue to protect the recreational values of the United States Forest Service's Juneau Falls Recreation Area.

DATES: *Effective Date:* October 8, 2011.

FOR FURTHER INFORMATION CONTACT: Robert L. Lloyd, Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513; 907–271–4682. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The purpose for which the withdrawal was first made requires this extension in order to continue to protect the recreational values of the Juneau Falls Recreation Area. The withdrawal extended by this order will expire on October 7, 2031, unless as a result of a review conducted prior to the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f), the Secretary of the Interior determines that the withdrawal shall be further extended. It has been determined that this action is not expected to have any significant effect on subsistence uses and needs pursuant to Section 810 of the Alaska National Interest Lands Conservation Act, 16 U.S.C. 3120.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, it is ordered as follows:

Public Land Order No. 6888 (56 FR 50661 (1991)), which withdrew approximately 320 acres of National Forest System land from settlement, sale, location, or entry under the public land laws, including the United States mining laws (30 U.S.C. ch 2), but not from leasing under the mineral leasing laws, to protect the recreational values of the Juneau Falls Recreation Area, is hereby extended for an additional 20-year period until October 7, 2031.

Authority: 43 CFR 2310.4.

Dated: June 7, 2011.

Wilma A. Lewis,

Assistant Secretary—Land and Minerals Management.

[FR Doc. 2011–15488 Filed 6–21–11; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection for 1029–0107

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request approval for the collection of information relating to Subsidence Insurance Program Grants.

DATES: Comments on the proposed information collection must be received by August 22, 2011, to be assured of consideration.

ADDRESSES: Comments may be mailed to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave, NW., Room 202—SIB, Washington, DC 20240. Comments may also be submitted electronically to *jtrelease@osmre.gov.*

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease, at (202) 208–2783 or via e-mail at *jtrelease@osmre.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8 (d)]. This notice identifies the information collection that OSM will be submitting to OMB for approval. This collection is contained in 30 CFR 887, Subsidence Insurance Program Grants. OSM will request a 3-year term of approval for each information collection activity.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control number for part 887 is 1029–0107 and is codified at 30 CFR 887.10. Responses are required to obtain a benefit.

Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSM's submission of the information collection request to OMB.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

This notice provides the public with 60 days in which to comment on the following information collection activity:

Title: 30 CFR 887—Subsidence Insurance Program Grants.

OMB Control Number: 1029–0107.

Summary: States and Indian tribes having an approved reclamation plan may establish, administer and operate self-sustaining State and Indian Tribe-administered programs to insure private property against damages caused by land subsidence resulting from underground mining. States and Indian tribes interested in requesting monies for their insurance programs would apply to the Director of OSM.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: States and Indian tribes with approved coal reclamation plans.

Total Annual Responses: 1.

Total Annual Burden Hours: 8.

Total Annual Non-Wage Costs: $0.

Dated: June 15, 2011.

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2011–15556 Filed 6–21–11; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection for 1029–0054

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request renewed authority for the collection of information relating to Abandoned mine reclamation funds.

DATES: Comments on the proposed information collection must be received by August 22, 2011, to be assured of consideration.

ADDRESSES: Comments may be mailed to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave., NW., Room 202–SIB, Washington, DC 20240. Comments may also be submitted electronically to *jtrelease@osmre.gov.*

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease, at (202) 208–2783, or electronically at *jtrelease@osmre.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8 (d)]. This notice identifies the information collection that OSM will be submitting to OMB for approval. This collection is contained in 30 CFR 872, Abandoned mine reclamation funds. OSM will request a 3-year term of approval for each information collection activity.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for Part 872 is 1029–0054 and is codified at 30 CFR 872.10. Responses are required to obtain a benefit.

Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSM's submission of the information collection request to OMB.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

This notice provides the public with 60 days in which to comment on the following information collection activity:

Title: 30 CFR 872—Abandoned Mine Reclamation Funds.

OMB Control Number: 1029–0054.

Summary: 30 CFR 872 establishes a procedure whereby States and Indian Tribes submit written statements announcing the State/Tribe's decision not to submit reclamation plans, and therefore, will not be granted AML funds.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: State and Tribal abandoned mine land reclamation agencies.

Total Annual Responses: 1.

Total Annual Burden Hours: 1.

Dated: June 15, 2011.

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2011–15558 Filed 6–21–11; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection for 1029–0091

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing that the information collection request for the requirements for surface coal mining and reclamation operations on Indian lands has been forwarded to the Office of Management and Budget (OMB) for review and comment. The information collection request describes the nature of the information collection and the expected burden and cost.

DATES: OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days. Therefore, public comments should be submitted to OMB by July 22, 2011, in order to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783, or electronically at *jtrelease@osmre.gov.* You may also review this collection by going to *http://www.reginfo.gov* (Information Collection Review, Currently Under Review, Agency is Department of the Interior, DOI–OSMRE).

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention:* Department of the Interior Desk Officer, by telefax at (202) 395–5806 or via e-mail to *OIRA_Docket@omb.eop.gov.* Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave, NW., Room 202–SIB, Washington, DC 20240, or electronically to *jtrelease@osmre.gov.* Please refer to OMB control number 1029–0091 in your correspondence.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSM has submitted a request to OMB to renew its approval of the collection of information for 30 CFR 750—Requirements for Surface Coal Mining and Reclamation Operations on Indian Lands. OSM is requesting a 3-year term of approval for this information collection activity.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 1029–0091. Applicants are required to respondent to obtain a benefit.

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments for this collection of information was published on April 7, 2011 (76 FR 19382). No comments were received. This notice provides the

public with an additional 30 days in which to comment on the following information collection activity:

Title: 30 CFR 750—Requirements for Surface Coal Mining and Reclamation Operations on Indian Lands.

OMB Control Number: 1029–0091.

Summary: Surface coal mining permit applicants who conduct or propose to conduct surface coal mining and reclamation operations on Indian lands must comply with the requirements of 30 CFR 750 pursuant to Section 710 of SMCRA.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: Applicants for coal mining permits.

Total Annual Responses: One new permit/significant revision annually.

Total Annual Burden Hours: 1,300 hours annually.

Total Annual Non-Wage Costs: $15,000 for filings fees for each new permit/significant revision.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the addresses listed under **ADDRESSES**. Please refer to the appropriate OMB control number 1029–0091 in your correspondence.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: June 15, 2011.

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2011–15559 Filed 6–21–11; 8:45 am]

BILLING CODE 4310–05–M

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–779]

Certain Flip-Top Vials and Products Using the Same; Notice of Institution of Investigation; Institution of Investigation Pursuant to 19 U.S.C. 1337

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on May 17, 2011, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of CSP Technologies, Inc., of Auburn, Alabama. Letters supplementing the complaint were filed on June 3 and June 7, 2011. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain flip-top vials and products using the same by reason of infringement of certain claims of U.S. Patent No. 7,537,137 (''the '137 patent''). The complaint further alleges that an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue an exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone 202–205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone 202–205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2011).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on June 16, 2011, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain flip-top vials and products using the same that infringe one or more of claims 1–5 and 7 of the '137 patent, and whether an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337;

(2) Pursuant to Commission Rule 201.50(b)(1), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties and other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue;

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: CSP Technologies, Inc., 960 W. Veterans Boulevard, Auburn, Alabama 36832.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served: Süd-Chemie AG, Lenbachplatz 6, 80333 Munich, Germany; Süd-Chemie, Inc., 1600 West Hill Street, Louisville, KY 40210; Airsec S.A.S., 6 Rue Louise Michel, 94600 Choisy le Roi, France.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Honorable Paul J. Luckern, Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the

Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d)–(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

The Süd-Chemie respondents may present to the presiding ALJ the matter raised in their June 6, 2011 confidential letter to the Commission.

By order of the Commission.

Issued: June 16, 2011.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–15534 Filed 6–21–11; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Clean Water Act

Notice is hereby given that on June 16, a proposed Consent Decree in *United States and the State of Nebraska* v. *Swift Beef Company,* Civil Action No. 8:11–cv–216 was lodged with the United States Court for the District of Nebraska. In this action, Plaintiffs the United States and State of Nebraska sought the penalties and injunctive relief for violations of the Clean Water Act (''CWA'') by Swift Beef Company (''Swift'') at a beef processing plant it owns and operates in Grand Island, Nebraska. Pursuant to the proposed Consent Decree, Defendants will pay to the United States and the State of Nebraska $1,300,000 in civil penalties and undertake injunctive measures designed to prevent future violations.

For 30 days after the date of this publication, the Department of Justice will receive comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either emailed to *pubcommentees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *Swift Beef Company,* Civil Action No. 8:11–cv–216 (D. Neb.), DJ Reference No. 90–5–1–1–09466.

During the public comment period, the Consent Decree may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the proposed consent decree may be obtained by mailing a request to the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611. When requesting a copy by mail, please enclose a check payable to the U.S. Treasury in the amount of $12.00 (25 cents per page reproduction cost). A copy may also be obtained by faxing or e-mailing a request to Tonia Fleetwood, *tonia.fleetwood@usdoj.gov,* fax number (202) 514–0097, phone confirmation number (202) 514–1547, and sending a check to the Consent Decree Library at the stated address.

Robert E. Maher, Jr.,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–15465 Filed 6–21–11; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on May 11, 2011, Chattem Chemicals, Inc., 3801 St. Elmo Avenue, Chattanooga, Tennessee 37409, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Gamma Hydroxybutyric Acid (2010).	I
Opium tincture (9630)	II
Opium, powdered (9639)	II
Opium, granulated (9640)	II
Tapentadol (9780)	II

The company plans to manufacture the listed controlled substances in bulk for distribution and sale to its customers. Regarding (9640) the company plans to manufacture another controlled substance for sale to its customers.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substance, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than August 22, 2011.

Dated: June 14, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–15478 Filed 6–21–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on May 4, 2011, Boehringer Ingelheim Chemicals Inc., 2820 N. Normandy Drive, Petersburg, Virginia 23805–9372, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Methadone (9250)	II
Methadone Intermediate (9254)	II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers for formulation into finished pharmaceuticals.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive,

Springfield, Virginia 22152; and must be filed no later than August 22, 2011.

Dated: June 13, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–15481 Filed 6–21–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated March 9, 2011, and published in the **Federal Register** on March 17, 2011, 76 FR 14689, Mallinckrodt Inc., 3600 North Second Street, St. Louis, Missouri 63147, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Codeine-N-oxide (9053)	I
Dihydromorphine (9145)	I
Difenoxin (9168)	I
Morphine-N-oxide (9307)	I
Normorphine (9313)	I
Norlevorphanol (9634)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Drug Schedule.	
Methylphenidate (1724)	II
Nabilone (7379)	II
Codeine (9050)	II
Diprenorphine (9058)	II
Etorphine HCL (9059)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Metopon (9260)	II
Dextropropoxyphene, bulk (9273)	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Opium, granulated (9640)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The firm plans to manufacture the listed controlled substances for internal use and for sale to other companies.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Mallinckrodt, Inc., to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Mallinckrodt, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: June 14, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–15482 Filed 6–21–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

156th Meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans; Notice of Meeting

Pursuant to the authority contained in Section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, the 156th open meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans; (also known as the ERISA Advisory Council) will be held on July 19–21, 2011.

The three-day meeting will take place in C–5515 Room 1–A, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. The purpose of the open meeting is for Advisory Council members to hear testimony from invited witnesses and to receive an update from the Employee Benefits Security Administration (EBSA). The meeting will run from 9 a.m. to approximately 5 p.m. on July 19 and from 8:30 a.m. to approximately 5 p.m. on July 20 and 21, with a one hour break for lunch each day. The EBSA update is scheduled for the afternoon of July 20, subject to change.

The Advisory Council will study the following issues: (1) Hedge Funds and Private Equity Investments, (2) Privacy and Security Issues Affecting Employee Benefit Plans (other than health care plans), and (3) Current Challenges and Best Practices for ERISA Compliance for 403(b) Plan Sponsors. The schedule for testimony and discussion of these issues generally will be one issue per day in the order noted above. Descriptions of these topics are available on the Advisory Council page of the EBSA Web site, at *http://www.dol.gov/ebsa/aboutebsa/erisa_advisory_council.html*.

Organizations or members of the public wishing to submit a written statement may do so by submitting 30 copies on or before July 12, 2011 to Larry Good, Executive Secretary, ERISA Advisory Council, U.S. Department of Labor, Suite N–5623, 200 Constitution Avenue, NW., Washington, DC 20210. Statements also may be submitted as e-mail attachments in text or pdf format transmitted to *good.larry@dol.gov*. It is requested that statements not be included in the body of the e-mail. Statements deemed relevant by the Advisory Council and received on or before July 12, 2011 will be included in the record of the meeting and available in the EBSA Public Disclosure room, along with witness statements. Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. Written statements submitted by invited witnesses also will be posted, without change, on the Advisory Council page of the EBSA Web site—*http://www.dol.gov/ebsa/*. Statements posted on the Internet can be retrieved by most Internet search engines.

Individuals or representatives of organizations wishing to address the Advisory Council should forward their requests to the Executive Secretary or telephone (202) 693–8668. Oral presentations will be limited to ten minutes, time permitting, but an extended statement may be submitted for the record. Individuals with disabilities who need special accommodations should contact the Executive Secretary by July 12 at the address indicated.

Signed at Washington, DC, this 17th day of June 2011.

Michael L. Davis,

Deputy Assistant Secretary, Employee Benefits Security Administration.

[FR Doc. 2011–15587 Filed 6–21–11; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0125]

Onsite Consultation Agreements; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits comments concerning its proposal to extend OMB approval of the information collection requirements contained in the Consultation Agreement regulations (hereinafter, the Onsite Consultation Program regulations) (29 CFR part 1908). The Onsite Consultation Program regulations specify services to be provided, and practices and procedures to be followed, by the State Onsite Consultation Programs. Information collection requirements set forth in the Onsite Consultation Program regulations are in two categories: *State Responsibilities* and *Employer Responsibilities.* Eight regulatory provisions require information collection activities by the State. The Federal government provides 90 percent of the funds for Onsite Consultation services delivered by the States, which result in the collections of information. Four requirements apply to employers and specify conditions for receiving the free Onsite Consultation services.

DATES: Comments must be submitted (postmarked, sent, or received) by August 22, 2011.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2011–0125, U.S. Department of Labor, Occupational Safety and Health Administration, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and OSHA docket number (OSHA–2011–0125) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You also may contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (i.e., employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)).

This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

Section 7(c)(1) of the Act authorizes the Secretary of Labor to, ''with the consent of any State or political subdivision thereof, accept and use the services, facilities, and personnel of any agency of such State or subdivision with reimbursement.'' Section 21(c) of the Act authorizes the Secretary of Labor (Secretary) to, ''consult with and advise employers and employees * * * as to effective means of preventing occupational illnesses and injuries.''

Additionally, Section 21(d) of the Act instructs the Secretary to ''establish and support cooperative agreements with the States under which employers subject to the Act may consult with State personnel with respect to the application of occupational safety and health requirements under the Act or under State plans approved under section 18 of the Act.'' This gives the Secretary authority to enter into agreements with the States to provide Onsite Consultation services, and establish rules under which employers may qualify for an inspection exemption. To satisfy the intent of these and other sections of the Act, OSHA codified the terms that govern cooperative agreements between OSHA and State governments whereby State agencies provide onsite consultation services to private employers to assist them in complying with the requirements of the OSH Act. The terms were codified as the Consultation Agreement regulations (29 CFR part 1908).

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other

technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend its approval of the information collection requirements contained in the Consultation Agreement regulations (29 CFR part 1908). The Agency is requesting an adjustment decrease of its current burden hour estimate associated with this ICR from 231,207 hours to 222,924 hours, a total decrease of 8,283 hours. These changes are based upon the current number of active projects and the most recently available number of visits conducted on an annual basis.

Type of Review: Extension of currently approved collections.

Title: Onsite Consultation Agreements.

OMB Number: 1218–0110.

Affected Public: Business or other for-profits.

Number of Respondents: 26,800.

Average Time per Response: Annually; monthly, quarterly, semi-annually, on occasion.

Total Responses: 111,620.

Frequency: Varies from 3 minutes (.05 hour) to replace the safe practice manual to 1 hour to develop a new manual.

Estimated Total urden Hours: 222,924.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for this ICR (Docket No. OSHA–2011–0125). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or a facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and date of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download through this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* Web site to submit comments and access the docket is available at the Web site's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available through the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, PhD, MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 5–2010 (75 FR 55355).

Signed at Washington, DC on June 17, 2011.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2011–15623 Filed 6–21–11; 8:45 am]

BILLING CODE 4510–26–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting Notice; Finance Committee of the Board of Directors

DATE AND TIME: The Finance Committee of the Legal Services Corporation will meet telephonically on June 27, 2011. The meeting will begin at 11 a.m., Eastern Standard Time, and will continue until the conclusion of the Committee's agenda.

LOCATION: F. William McCalpin Conference Center, Legal Services Corporation Headquarters Building, 3333 K Street, NW., Washington, DC 20007.

PUBLIC OBSERVATION: Members of the public who are unable to attend but wish to listen to the public proceedings may do so by following the telephone call-in directions provided below but are asked to keep their telephones muted to eliminate background noises. From time to time, the presiding Chair may solicit comments from members of the public present for the meeting.

CALL–IN DIRECTIONS:

- Call toll-free number: 1–866–451–4981;
- When prompted, enter the following numeric pass code: 5907707348
- When connected to the call, please ''MUTE'' your telephone immediately.

STATUS OF MEETING: Open.

Matters To Be Considered

Open Session

1. Approval of agenda.
2. Presentation of LSC's Financial Reports for the period ending May 31, 2011.
3. LSC Finance Committee and LSC Staff discussion regarding criteria for the Committee's recommendation to the LSC Board for the FY 2013 budget 'mark'.
4. Consider and act on other business.
5. Consider and act on adjournment of meeting.

CONTACT PERSON FOR INFORMATION: Katherine Ward, Executive Assistant to the Vice President & General Counsel, at (202) 295–1500. Questions may be sent by electronic mail to *FR_NOTICE_QUESTIONS@lsc.gov.*

ACCESSIBILITY: LSC complies with the American's with Disabilities Act and Section 504 of the 1973 Rehabilitation Act. Upon request, meeting notices and materials will be made available in alternative formats to accommodate individuals with disabilities. Individuals who need other accommodations due to disability in order to attend the meeting in person or telephonically should contact Katherine Ward, at (202) 295–1500 or *FR_NOTICE_QUESTIONS@lsc.gov,* at least 2 business days in advance of the meeting. If a request is made without advance notice, LSC will make every effort to accommodate the request but cannot guarantee that all requests can be fulfilled.

Dated: June 20, 2011.

Victor M. Fortuno,

Vice President & General Counsel.

[FR Doc. 2011–15749 Filed 6–20–11; 4:15 pm]

BILLING CODE 7050–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Revision of an Existing Information Collection, USAJOBS

AGENCY: U.S. Office of Personnel Management.

ACTION: 60-Day Notice and request for comments.

SUMMARY: The U.S. Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a revised information collection request (ICR) 3206–0219, USAJOBS. As required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection. In particular, we invite comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

DATES: Comments are encouraged and will be accepted until August 22, 2011. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the U.S. Office of Personnel Management, Employment Services, USAJOBS, 1900 E Street, NW., Washington, DC 20415, Attention: Patricia Stevens, or send them via electronic mail to *patricia.stevens@opm.gov.*

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the U.S. Office of Personnel Management, Employment Services, USAJOBS, 1900 E Street, NW., Washington, DC 20415, Attention: Patricia Stevens, or by sending a request via electronic mail to *patricia.stevens@opm.gov.*

SUPPLEMENTARY INFORMATION: USAJOBS is the official Federal Government source for Federal jobs and employment information. The Applicant Profile and Resume Builder are two components of the USAJOBS application system. USAJOBS reflects the minimal critical elements collected across the Federal Government to assess an applicant's qualifications for Federal jobs under the authority of sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of title 5, United States Code. We are revising the Information Collection at this time, in part, to permit the migration of USAJOBS to a new platform. In addition, this revision proposes to:

(A.) Discontinue the use of the Application for Federal Employment Optional Form 612. This action is being taken to facilitate a more seamless employment application process for both Federal agencies and job seekers, consistent with the goals of Federal hiring reform.

(B.) Revise the collection of Demographic Information on Applicants by removing the sourcing question ''How did you learn about this position?'' along with the pre-populated answer choices provided for this question.

(C.) Add basic eligibility questions to the applicant profile as well as optional questions to the Applicant Profile in USAJOBS that will allow applicants to self-identify (subject to subsequent verification by the appointing agency) as eligible for certain special hiring authorities. This is expected to streamline some hiring actions by allowing agencies to search for resumes of applicants who have volunteered information about their eligibility under special hiring authorities. Information volunteered by applicants about their potential eligibility under one or more special hiring authorities will be stored in USAJOBS and will only become visible to agencies that are considering filling a job using a special hiring authority. In that case, the hiring agency will be able to search USAJOBS for potential applicants who have chosen to indicate that they believe they are eligible to be selected under the special authority the agency seeks to use. The special hiring authorities are as follows:

1. Employment of a disabled veteran who has a compensable service-connected disability of 30 percent or more

   5 CFR 316.402(b)(4) Temporary Appointment,

   5 CFR 316.302(b)(4) Term Appointment.

2. Military Spouse—Executive Order 13473, Noncompetitive Appointing Authority for Certain Military Spouses

   5 CFR 315.612.

Non-competitive appointment of certain former overseas military spouse employees

   5 CFR 315.608.

3. Schedule ''A''—Excepted Service—Appointment of Persons with Disabilities

   5 CFR 213.3102(u).

4. Veterans Employment Opportunities Act (VEOA)

   5 CFR 315.611.

5. Veterans Recruitment Appointment (VRA)

   5 CFR 307,

   5 CFR 316.302(b)(2) Term Appointment,

   5 CFR 316.402(b)(2) Temporary Appointment.

6. Employment of disabled veterans who completed a training course under Chapter 31 of title 38 United States Code

   5 CFR 315.604.

Applicants who do not choose to use this opportunity to volunteer information about their eligibility under a special hiring authority may still choose to apply for jobs, as they are announced, under any of these special hiring authorities for which they are eligible. If applicants volunteer to provide information through the Web site about the special hiring authorities for which they believe they are eligible, then agencies that are searching for potential applicants to hire under one of these authorities may be able to locate their resume through USAJOBS and invite them to apply. Otherwise, this information will be retained in the USAJOBS database and not disclosed. We estimate it will take approximately 38 minutes to initially complete the Resume Builder, depending on the amount of information the applicant wishes to include, and approximately five minutes to initially complete the Applicant Profile. We estimate over 3,500,000 new USAJOBS accounts will be submitted annually. The total annual estimated burden is 2,508,333 hours.

U.S. Office of Personnel Management.

John Berry,

Director.

[FR Doc. 2011–15595 Filed 6–21–11; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Disabled Dependent Questionnaire, RI 30–10

AGENCY: U.S. Office of Personnel Management.

ACTION: 30-Day Notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on an existing information collection request (ICR) 3206–0179, Disabled Dependent Questionnaire. As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection. The information collection was previously published in the **Federal Register** on April 5, 2011 at Volume 76 FR 18812 allowing for a 60-day public comment period. No comments were received for this information collection. The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

DATES: Comments are encouraged and will be accepted until July 22, 2011. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: RI 30–10, Disabled Dependent Questionnaire, is used to collect sufficient information about the medical condition and earning capacity for the Office of Personnel Management to be able to determine whether a disabled adult child is eligible for health benefits coverage and/or survivor annuity payments under the Civil Service Retirement System or the Federal Employees Retirement System.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Disabled Dependent Questionnaire.

OMB Number: 3206–0179.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 2,500.

Estimated Time per Respondent: 1 hour.

Total Burden Hours: 2,500.

U.S. Office of Personnel Management.

John Berry,

Director.

[FR Doc. 2011–15600 Filed 6–21–11; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Standard Form 2809, Health Benefits Election Form

AGENCY: U.S. Office of Personnel Management.

ACTION: 30-Day Notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a revised information collection request (ICR) 3206–0160, Health Benefits Election Form. As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection. The information collection was previously published in the **Federal Register** on July 9, 2010 at Volume 75 FR 39587 allowing for a 60-day public comment period. We received comments from one organization. Based on the comments, several changes were made to the form including changes that make it consistent with the Affordable Care Act (Pub. L. 111–48). The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

DATES: Comments are encouraged and will be accepted until July 22, 2011. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: The Health Benefits Election Form is used

by Federal employees, annuitants other than those under the Civil Service Retirement System (CSRS) and the Federal Employees Retirement System (FERS) including individuals receiving benefits from the Office of Workers' Compensation Programs, former spouses eligible for benefits under the Spouse Equity Act of 1984, and separated employees and former dependents eligible to enroll under the Temporary Continuation of Coverage provisions of the FEHB law (5 U.S.C. 8905a). A different form (OPM 2809) is used by CSRS and FERS annuitants whose health benefit enrollments are administered by OPM's Retirement Operations.

Analysis

Agency: Insurance Operations, Healthcare and Insurance, Office of Personnel Management.
Title: Health Benefits Election Form.
OMB Number: 3206–0160.
Frequency: On occasion.
Affected Public: Individuals or Households.
Number of Respondents: 18,000.
Estimated Time per Respondent: 30 minutes.
Total Burden Hours: 9,000.

U.S. Office of Personnel Management.

John Berry,

Director.

[FR Doc. 2011–15596 Filed 6–21–11; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Life Insurance Election, Standard Form 2817

AGENCY: U.S. Office of Personnel Management.

ACTION: 30-Day Notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a revised information collection request (ICR) 3206–0230, Life Insurance Election. As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection. The information collection was previously published in the **Federal Register** on April 5, 2011 at Volume 76 FR 18810 allowing for a 60-day public comment period. No comments were received for this information collection. The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

DATES: Comments are encouraged and will be accepted until July 22, 2011. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: Standard Form 2817 is used by Federal employees and assignees (those who have acquired control of an employee/annuitant's coverage through an assignment or ''transfer'' of the ownership of the life insurance). Clearance of this form for use by active Federal employees is not required according to the Paperwork Reduction Act (Pub. L. 98–615). The Public Burden Statement meets the requirements of 5 CFR 1320.8(b)(3). Therefore, only the use of this form by assignees, *i.e.* members of the public, is subject to the Paperwork Reduction Act.

Analysis

Agency: Retirement Operations, Healthcare and Insurance, Office of Personnel Management.
Title: Life Insurance Election, Federal Employees' Group Life Insurance Program.
OMB Number: 3206–0230.
Frequency: On occasion.
Affected Public: Individuals or Households.
Number of Respondents: 150.
Estimated Time per Respondent: 15 minutes.
Total Burden Hours: 37.5.

U.S. Office of Personnel Management.

John Berry,

Director.

[FR Doc. 2011–15598 Filed 6–21–11; 8:45 am]

BILLING CODE 6325–38–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2011–65; Order No. 746]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently-filed Postal Service request to enter into an additional Global Reseller Expedited Package contract. This document invites public comments on the request and addresses several related procedural steps.

DATES: *Comments are due:* June 24, 2011.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Notice of Filing
III. Ordering Paragraphs

I. Introduction

On June 14, 2011, the Postal Service filed a notice announcing that it has entered into an additional Global Reseller Expedited Package (GREP) contract.[1] The Postal Service believes the instant contract is functionally equivalent to the GREP baseline agreement and is supported by Governors' Decision No. 10–1 attached to the Notice and originally filed in Docket No. CP2010–36. *Id.* at 1, Attachment 3. The Notice explains that Order No. 445, which established GREP Contracts 1 as a product, also authorized functionally equivalent agreements to be included within the product, provided that they meet the requirements of 39 U.S.C. 3633. *Id.* at 1–2. Additionally, the Postal Service requested to have the contract in Docket No. CP2010–36 serve as the baseline contract for future functional equivalence analyses of the GREP Contracts 1 product.

The instant contract. The Postal Service filed the instant contract pursuant to 39 CFR 3015.5. In addition, the Postal Service contends that the instant contract is in accordance with Order No. 445. The instant contract is a renewal of the first GREP contract, filed in Docket No. CP2010–36, which is scheduled to expire on June 30, 2011. Notice at 1. The Postal Service will notify the mailer of the effective date within 30 days after all necessary regulatory approvals have been received. The contract will remain in effect until January 31, 2012, or a date in January 2012 prior to the Postal Service's publication of price changes for its Express Mail International and/or Priority Mail International products. *Id.* at 3. It may, however, be terminated by either party on not less than 30 days' written notice. *Id.* Attachment 1 at 5.

In support of its Notice, the Postal Service filed four attachments as follows:

- Attachment 1—a redacted copy of the contract and applicable annexes;
- Attachment 2—a certified statement required by 39 CFR 3015.5(c)(2);
- Attachment 3—a redacted copy of Governors' Decision No. 10–1, which establishes prices and classifications for GREP contracts, a description of applicable GREP contracts, formulas for prices, an analysis of the formulas, and certification of the Governors' vote; and
- Attachment 4—an application for non-public treatment of materials to maintain redacted portions of the contract and supporting documents under seal.

The Notice advances reasons why the instant GREP contract fits within the Mail Classification Schedule language for GREP Contracts 1. The Postal Service identifies general contract terms that distinguish the instant contract from the baseline GREP agreement. It states that the instant contract differs from the contract in Docket No. CP2010–36 pertaining to revisions or clarification of terms, *e.g.,* definition of qualifying mail, discounts offered by the reseller, minimum revenue, periodic review of minimum commitment, term, assignment, number of rate groups, and solicitation of reseller's customers. *Id.* at 4–6. The Postal Service states that the differences, which include price variations based on updated costing information and volume commitments, do not alter the contract's functional equivalency. *Id.* at 4. The Postal Service asserts that ''[b]ecause the agreement incorporates the same cost attributes and methodology, the relevant characteristics of this GREP contract are similar, if not the same, as the relevant characteristics of the contract filed in Docket No. CP2010–36.'' *Id.*

The Postal Service concludes that its filing demonstrates that the new GREP contract complies with the requirements of 39 U.S.C. 3633 and is functionally equivalent to the baseline GREP contract. It states that the differences do not affect the services being offered or the fundamental structure of the contract. Therefore, it requests that the instant contract be included within the GREP Contracts 1 product. *Id.* at 6.

II. Notice of Filing

The Commission establishes Docket No. CP2011–65 for consideration of matters related to the contract identified in the Postal Service's Notice.

Interested persons may submit comments on whether the Postal Service's contract is consistent with the policies of 39 U.S.C. 3632, 3633, or 3642. Comments are due no later than June 24, 2011. The public portions of this filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints John P. Klingenberg to serve as Public Representative in the captioned proceeding.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2011–65 for consideration of matters raised by the Postal Service's Notice.

2. Comments by interested persons in this proceeding are due no later than June 24, 2011.

3. Pursuant to 39 U.S.C. 505, John P. Klingenberg is appointed to serve as the officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2011–15506 Filed 6–21–11; 8:45 am]

BILLING CODE 7710–FW–P

[1] Notice of United States Postal Service of Filing a Functionally Equivalent Global Reseller Expedited Package Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, June 14, 2011 (Notice).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 29694; File No. 812–13843]

Highmark Funds and Highmark Capital Management, Inc.

June 16, 2011.

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 rule 12d1–2(a) under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit open-end management investment companies relying on rule 12d1–2 under the Act to invest in certain financial instruments.

APPLICANTS: HighMark Funds (''Trust'') and HighMark Capital Management, Inc. (''HCM,'' and together with the Trust, ''Applicants'').

FILING DATES: The application was filed on November 10, 2010, and amended on April 29, 2011.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on July 11, 2011 and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090; *Applicants:* c\o Gregory C. Davis, *esq.,* Ropes & Gray LLP, Three Embarcadero Center, San Francisco, California 94111–4006.

FOR FURTHER INFORMATION CONTACT: Emerson S. Davis, Senior Counsel, at (202) 551–6868, or Janet M. Grossnickle, Assistant Director, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Trust is organized as a Massachusetts business trust and is registered with the Commission as an open-end management investment company. HCM, a California corporation and wholly-owned subsidiary of Union Bank, N.A, is registered as an investment adviser under the Investment Advisers Act of 1940, as amended.

2. Applicants request the exemption to the extent necessary to permit any existing or future series of the Trust and any other registered open-end management investment company that is advised by HCM or any person controlling, controlled by or under common control with HCM (any such adviser or HCM, an ''Adviser'') that invests in other registered open-end management investment companies (''Underlying Funds'') in reliance on section 12(d)(1)(G) of the Act and rule 12d1–2 under the Act, and which is also eligible to invest in securities (as defined in section 2(a)(36) of the Act) in reliance on rule 12d1–2 under the Act (each a ''Fund of Funds''), to also invest, to the extent consistent with its investment objective, policies, strategies and limitations, in financial instruments that may not be securities within the meaning of section 2(a)(36) of the Act (''Other Investments'').[1]

3. Consistent with its fiduciary obligations under the Act, each Fund of Funds' board of trustees or directors will review the advisory fees charged by the Fund of Funds' investment adviser to ensure that they are based on services provided that are in addition to, rather than duplicative of, services provided pursuant to the advisory agreement of any investment company in which the Fund of Funds may invest.

Applicants' Legal Analysis

1. Section 12(d)(1)(A) of the Act provides that no registered investment company (''acquiring company'') may acquire securities of another investment company (''acquired company'') if such securities represent more than 3% of the acquired company's outstanding voting stock or more than 5% of the acquiring company's total assets, or if such securities, together with the securities of other investment companies, represent more than 10% of the acquiring company's total assets. Section 12(d)(1)(B) of the Act provides that no registered open-end investment company may sell its securities to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company's voting stock, or cause more than 10% of the acquired company's voting stock to be owned by investment companies and companies controlled by them.

2. Section 12(d)(1)(G) of the Act provides that section 12(d)(1) will not apply to securities of an acquired company purchased by an acquiring company if: (a) The acquired company and acquiring company are part of the same group of investment companies; (b) the acquiring company holds only securities of acquired companies that are part of the same group of investment companies, government securities, and short-term paper; (c) the aggregate sales loads and distribution-related fees of the acquiring company and the acquired company are not excessive under rules adopted pursuant to section 22(b) or section 22(c) of the Act by a securities association registered under section 15A of the Securities Exchange Act of 1934 or by the Commission; and (d) the acquired company has a policy that prohibits it from acquiring securities of registered open-end investment companies or registered unit investment trusts in reliance on section 12(d)(1)(F) or (G) of the Act.

3. Rule 12d1–2 under the Act permits a registered open-end investment company or a registered unit investment trust that relies on section 12(d)(1)(G) of the Act to acquire, in addition to securities issued by another registered investment company in the same group of investment companies, government securities, and short-term paper: (a) Securities issued by an investment company that is not in the same group of investment companies, when the acquisition is in reliance on section 12(d)(1)(A) or 12(d)(1)(F) of the Act; (b) securities (other than securities issued by an investment company); and (c) securities issued by a money market fund, when the acquisition is in reliance on rule 12d1–1 under the Act. For the purposes of rule 12d1–2, ''securities'' means any security as defined in section 2(a)(36) of the Act.

4. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction from any provision of the Act, or from any rule under the Act, if 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.

5. Applicants state that the proposed arrangement would comply with the provisions of rule 12d1–2 under the Act, but for the fact that the Funds of Funds may invest a portion of their assets in Other Investments. Applicants request an order under section 6(c) of the Act for an exemption from rule 12d1–2(a) to allow the Fund of Funds to invest in Other Investments. Applicants assert that permitting the Funds of Funds to invest in Other Investments as described in the application would not raise any of the concerns that the requirements of section 12(d)(1) were designed to address.

Applicants' Condition

Applicants agree that the order granting the requested relief will be subject to the following condition:

Applicants will comply with all provisions of rule 12d1–2 under the Act, except for paragraph (a)(2) to the extent that it restricts any Fund of Funds from investing in Other Investments as described in the application.

For the Commission, by the Division of Investment Management, under delegated authority.

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–15552 Filed 6–21–11; 8:45 am]

BILLING CODE 8011–01–P

[1] Every existing entity that currently intends to rely on the requested order is named as an applicant. Any existing or future entity that relies on the order in the future will do so only in accordance with the terms and conditions in the application.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64687; File No. SR–FINRA–2011–013]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, Establishing a Registration Category, Qualification Examination and Continuing Education Requirements for Certain Operations Personnel, and Adopt FINRA Rule 1250 (Continuing Education Requirements) in the Consolidated FINRA Rulebook

June 16, 2011.

I. Introduction

On March 4, 2011, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt FINRA Rule 1230(b)(6) to establish a registration category and qualification examination requirement for certain operations personnel. The proposed rule change also would adopt continuing education requirements for such operations personnel and adopt NASD Rule 1120 (Continuing Education Requirements) as FINRA Rule 1250 (Continuing Education Requirements) in the consolidated FINRA rulebook with minor changes. The proposed rule change was published for comment in the **Federal Register** on March 18, 2011.[3] The Commission received seventeen comment letters on the proposed rule change.[4] On June 15, 2011, the Commission received from FINRA a Response to Comments and Partial Amendment No. 1 to the proposed rule change.[5] The Commission is publishing this notice and order to solicit comment on Amendment No. 1 and to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description of Proposed Rule Change and Summary of Comments

As described in Exchange Act Release No. 64080,[6] FINRA is proposing to adopt FINRA Rule 1230(b)(6) to establish a registration category and qualification examination requirement for certain operations personnel. The proposed rule change also would adopt continuing education requirements for such operations personnel and adopt NASD Rule 1120 (Continuing Education Requirements) as FINRA Rule 1250 (Continuing Education Requirements) in the consolidated FINRA rulebook with minor changes. All of the commenters opposed the rule in whole or in part.

FINRA's responses to comments and explanation of the changes to the proposed rule change made by Amendment No. 1 are described below.

A. Covered Persons

Proposed FINRA Rule 1230(b)(6)(A) sets forth three categories of persons that would be subject to the proposed registration, qualification and continuing education requirements for an Operations Professional.[7] These categories are:

(1) Senior management with responsibility over the covered functions;[8]

(2) Supervisors, managers or other persons responsible for approving or authorizing work, including work of other persons, in direct furtherance of the covered functions; and

(3) Persons with the authority or discretion materially to commit a member's capital in direct furtherance of the covered functions or to commit a member to any material contract or agreement (written or oral) in direct furtherance of the covered functions.

One commenter supports limiting the scope of covered persons to supervisory personnel.[9] Three commenters are concerned about the impact of the proposed rule change on arrangements between members and third-party service providers, and request that FINRA limit the proposal to ''associated persons'' of a member.[10] One such commenter requests an analysis of FINRA rules, the Securities Exchange Act of 1934 (''Exchange Act'') and SEC rules to allay concerns of unexpected or unintended applications, interpretations and consequences with respect to sweeping employees of third-party service providers into the categories of associated and registered persons.[11]

Another commenter states that limiting the proposal to associated persons would assist members in interpreting the proposed rule and resolve complicated jurisdictional and practical issues, since requiring firms to license employees of third-parties raises many complex issues including contract negotiations with vendors determining which member firm should sponsor the registrations of a vendor's employees and which firm should ''supervise'' such employees when a single vendor serves multiple members.[12] Additionally, the commenter suggests changing the title of proposed Rule 1230(b)(6)(A) from ''Requirement'' to ''Covered Persons'' and limiting this provision to the following: ''[e]ach of the following associated persons of a member, charged with responsibility for overseeing and protecting the functional and control integrity of the covered functions in paragraph (b)(6)(B) of this Rule, shall be required to register as an Operations Professional.'' [13] The commenter notes that this language, in part, mirrors descriptive language used

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 64080 (March 14, 2011), 76 FR 15012 (March 18, 2011) (''Notice'').

[4] *See* comment letters submitted by Corey N. Callaway, CEO, Callaway Financial Services, Inc., dated March 22, 2011 (''Callaway''); Jeffrey B. Williams, Vice President & Chief Compliance Officer, Northwestern Mutual Investment Services, LLC, dated March 25, 2011 (''NMIS''); Z. Jane Riley, Chief Compliance Officer, The Leaders Group, Inc./TLG Advisors, Inc., dated April 6, 2011 (''TLG''); Matthew J. Gavaghan, Associate General Counsel, Janney Montgomery Scott LLC, dated April 8, 2011 (''JMS''); Pam Lewis Marlborough, Associate General Counsel, TIAA–CREF Individual & Institutional Services, LLC, dated April 8, 2011 (''T–C Services—1''); James Livingston, President/Chief Executive Officer, National Planning Holdings, Inc., dated April 8, 2011 (''NPH''); D. Grant Vingoe, Partner, Arnold & Porter LLP, dated April 8, 2011 (''A&P''); David T. Bellaire, General Counsel and Director of Government Affairs, Financial Services Institute, dated April 8, 2011 (''FSI''); Joan Hinchman, Executive Director, CEO and President, National Society of Compliance Professionals Inc., dated April 8, 2011 (''NSCP''); Ronald C. Long, Director of Regulatory Affairs, Wells Fargo Advisors, LLC, dated April 8, 2011 (''WFA''); Bari Havlik, SVP and Chief Compliance Officer, Charles Schwab & Co., Inc., dated April 8, 2011 (''Schwab''); Sutherland Asbill & Brennan LLP, on behalf of the Committee of Annuity Insurers, dated April 8, 2011 (''Sutherland''); Jesse D. Hill, Director of Regulatory Relations, Edward Jones, dated April 8, 2011 (''Edward Jones''); James T. McHale, Managing Director and Associate General Counsel, SIFMA, dated April 29, 2011 (''SIFMA''); David S. Massey, President, North American Securities Administrators Association, dated May 2, 2011 (''NASAA''); John W. Curtis, Managing Director, General Counsel—Global Compliance, Goldman, Sachs & Co., dated May 3, 2011 (''Goldman''); and Pam Lewis Marlborough, Associate General Counsel, TIAA–CREF Individual & Institutional Services, LLC, dated May 4, 2011 (''T–C Services—2'').

[5] *See* letter from Erika A. Lazar, FINRA, to Elizabeth Murphy, Secretary, SEC, dated June 15, 2011 (''Response Letter''). The text of the proposed rule Amendment No. 1 and FINRA's Response Letter are available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA, on the Commission's Web site at *http://www.sec.gov,* and at the Commission's Public Reference Room.

[6] *See* note 3 *supra.*

[7] *See* Notice, note 3 *supra.*

[8] Covered functions are discussed further in Part B below.

[9] TLG.

[10] NSCP, Schwab and SIFMA.

[11] Schwab.

[12] SIFMA.

[13] SIFMA.

by FINRA in the Notice. The commenter believes that the proposed rule change significantly expands FINRA's regulation of outsourced activities and requests that such authority be addressed as part of FINRA's outsourcing proposal.[14] Another commenter requests that FINRA limit covered persons to employees of a member, given that the current proposal would result in a great deal of subjectivity by members to identify covered persons, and in light of a member's supervisory obligations for outsourced functions under current FINRA guidance.[15]

FINRA responded that, as stated in the Notice, it believes that any person who meets the definition of a covered person in proposed Rule 1230(b)(6)(A) and engages in one or more of the covered functions in proposed Rule 1230(b)(6)(B) on behalf of a member must register as an Operations Professional, regardless of whether such person works internally at a member, an affiliate or third-party service provider because they are performing regulated broker-dealer functions on behalf of a member.[16] FINRA believes that covered persons interact in areas of a member that have a meaningful connection to client funds, accounts and transactions and are involved in significant decisions that can raise compliance issues for a firm.[17] Also, FINRA states that, as noted in the Notice, the proposed rule change does not alter the definition of an associated person; rather, it imposes registration, qualification examination and continuing education requirements on persons who meet the depth of personnel criteria and engage in one or more of the covered functions on behalf of a member.[18]

In its Response Letter, FINRA stated that the alternative rule text suggested by the commenter above [19] would not change the application of the proposed rule because, by virtue of their activities on behalf of the member, the covered persons have been and continue to be associated persons of such member.[20] FINRA stated that Associated person status is not determined at the discretion of a member firm based on the location from which particular personnel are performing functions on behalf of the firm; associated person status attaches to persons who are involved in the securities and investment banking business of a member firm and the covered functions in the proposed rule represent a part of that business of a member firm.[21] Moreover, FINRA notes that the scope of covered persons and covered functions set forth in proposed Rule 1230(b) is not exhaustive in terms of who may be considered an associated person of the member based on the nature of the operations activities being conducted on behalf of a member.[22] Rather, FINRA has made a determination that the persons subject to the proposed rule change are engaged in members' operations activities of such significance to require registration, qualification examination and continuing education requirements.[23] FINRA, however, notes that it is proposing to amend the title of paragraph (b)(6)(A) to proposed Rule 1230 to ''Covered Persons'' from ''Requirement'' to better reflect the content of the paragraph.[24]

Two commenters note the prevalence of shared resources models, in which shared services are provided to different legal entities within a large financial company, and the challenges raised by the proposed rule for firms in determining whether certain individuals previously not identified as associated persons would now be subject to the rules applicable to associated and registered persons.[25] One commenter requests clarification that only the Operations Professional and not his or her supervisors or subordinates would be considered associated persons of the member.[26] The commenter also suggests that FINRA's jurisdiction should not extend to any of the affiliated entities that may employ an Operations Professional.[27]

FINRA responds that members are free to use shared services models because associated person status does not turn on employment.[28] FINRA notes that the proposed rule does not define associated persons; rather, it defines which associated persons involved in the operation of a member's investment banking and securities business must register as an Operations Professional.[29] FINRA says that firms must view each person's responsibilities in connection with the covered functions independently to determine who must register.[30]

One commenter believes the proposed rule change is unfairly burdensome on small firms, since it will make it impossible to obtain and retain employees, in particular the potential registration of independent Information Technology (''IT'') personnel and other similarly outsourced functions.[31] Another commenter states that rather than requiring individuals at both the introducing broker-dealer and clearing firm to register and test under the proposed rule, FINRA should amend FINRA Rule 4311 (Carrying Agreements) to require that parties to a clearing agreement specifically designate the party responsible for any shared functions in the clearing agreement to reduce the economic and resource burden of requiring all individuals who meet the criteria of a covered function to register under the proposal.[32]

As further discussed in the Notice, FINRA does not believe that small firms would be overly burdened by the proposed rule change.[33] FINRA anticipates that many persons who would be subject to the new Operations Professional registration category would qualify for the proposed exception from the qualification examination based on existing registrations, and FINRA would not assess a separate registration fee for persons relying on the proposed exception to register as Operations Professionals.[34] FINRA says, moreover, that the impact of the proposed rule change is expected to be minimal as the majority of the covered functions are typically performed by a carrying and clearing firm pursuant to a clearing arrangement.[35] In such cases, it may be possible for a small firm to rely on limited persons, perhaps the Financial and Operations Principal, to liaise with the carrying and clearing firm regarding those covered functions. FINRA stated that, as further discussed in the Notice, a covered person would not be considered an associated person of both the introducing and clearing firms based solely on functions performed pursuant to a carrying agreement approved under FINRA Rule 4311 (Carrying Agreements).[36] FINRA indicated that it would not expect dual registration as an Operations Professional in such cases.[37]

[14] SIFMA. *See also Regulatory Notice* 11–14 (Third-Party Service Providers).

[15] NSCP.

[16] Response Letter.

[17] *Id.*

[18] *Id.*

[19] *See supra* note 13 and accompanying text.

[20] Response Letter.

[21] *Id.*

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] NPH and Sutherland.

[26] Sutherland.

[27] Sutherland.

[28] Response Letter.

[29] *Id.*

[30] *Id.*

[31] Callaway.

[32] FSI. The SEC recently approved new FINRA Rule 4311. *See* Exchange Act Release No. 63999 (Mar. 1, 2011), 76 FR 12380 (Mar. 7, 2011). The rule becomes effective on August 1, 2011. *See Regulatory Notice* 11–26.

[33] Response Letter.

[34] *Id.*

[35] *Id.*

[36] *Id.*

[37] *Id.*

In addition, as further discussed in Section F below, the proposed rule change provides a 120-day grace period for non-Day-One Professionals associated with a non-clearing firm to pass a qualification examination.[38]

One commenter believes that the depth of personnel and covered functions are so loosely worded as to potentially capture activities performed in a number of areas of a member firm, including, but not limited to, Operations, Finance, Treasury, Information Technology (''IT''), Information Security (''IS''), Marketing and Sales.[39] FINRA agrees with the commenter that covered persons may be designated in multiple areas of a member (or outside the member) depending on the business structure of the firm.[40] FINRA stated that the proposed rule change is function-based and, therefore, not conditioned upon an individual's relationship to a particular department within a firm.[41] FINRA said that, in developing the proposed rule change and with the input of industry representatives, they identified operations functions that significantly impact a member's business and have the potential to harm the member, a customer, the integrity of the marketplace or the public.[42]

Several commenters have concerns regarding the application of proposed Rule 1230(b)(6)(A)(i) (''[s]enior management with responsibility over the covered functions'') to senior management up the chain of command. One commenter questions how far up the chain of command this provision is intended to go (*i.e.,* whether it is intended to reach the CEO) and recommends limiting it to persons with ''direct'' or ''primary'' responsibility for the covered functions.[43] The commenter requests express guidance that a firm's Chief Information Officer, Chief Technology Officer or other senior executives responsible for a firm's overall IT function would not be required to register if not directly or primarily responsible for a covered function.[44] Another commenter suggests the proposed rule be limited to ''senior management directly responsible for supervising or overseeing the covered functions to ensure integrity and compliance with the Federal securities laws and regulations and FINRA rules.''[45] The commenter notes that a firm's Chief Technology Officer and other technology or information security executives may be deemed senior management responsible for a covered function, even though their roles are supportive in nature, and other executives who hold other licenses would also be required to register (*i.e.,* Marketing and Sales executives who design customer confirms or assist in customer data collection at account opening).[46] The commenter posits that if these executives are required to register, individuals down the chain of command would also be subject to the proposal, which the commenter finds unnecessary and redundant.[47] The commenter also requests that the SEC not approve the proposed rule change unless FINRA limits covered persons to those individuals with ''significant responsibilities or substantial decision-making authority regarding operational issues.''[48]

To clarify proposed Rule 1230(b)(6)(A)(i), FINRA is amending the proposed rule change to provide that the first category of covered persons would include senior management with *direct* responsibility over the covered functions.[49] FINRA states that it believes this proposed change will better enable members to identify who must register as an Operations Professional so that senior management with an indirect relationship to the covered functions are not subject to the proposed registration, qualification examination and continuing education requirements; however, members must ensure senior management that sign off on the covered functions and who are responsible for ensuring the covered functions are executed in compliance with the Federal securities laws and regulations and FINRA rules are properly registered.[50] FINRA states that the proposal's aim is not to require registration for personnel with an indirect connection to the covered functions.[51]

One commenter suggests that proposed Rule 1230(b)(6)(A)(ii) (''[s]upervisors, managers or other persons responsible for approving or authorizing work, including work of other persons, in direct furtherance of the covered functions'') is too broad and may include employees below the decision-making level and further suggests replacing this provision with language in the Notice: ''[p]ersons who are directly responsible for overseeing that tasks within the covered functions are performed correctly in accordance with industry rules, firm protocols, policies and procedures, and who are charged with protecting the functional and control integrity of the covered functions for a member.''[52] The commenter believes that this language also would make proposed Rule 1230(b)(6)(A)(iii) unnecessary.[53]

To clarify proposed Rule 1230(b)(6)(A)(ii), FINRA is proposing to amend the proposed rule to provide that the second category of covered persons would include any person designated by senior management specified in Rule 1230(b)(6)(A)(i) as a supervisor, manager or other person responsible for approving or authorizing work, including work of other persons, in direct furtherance of each of the covered functions, as applicable, provided that there is sufficient designation of such persons by senior management to address each of the applicable covered functions.[54] FINRA believes the change to proposed Rule 1230(b)(6)(A)(ii) helps to clarify that senior management of a firm may designate the next tier of management or other persons responsible for approving or authorizing work in direct furtherance of the covered functions, in accordance with reasonable business practices.[55] In addition, FINRA stated that any person who qualifies as a covered person is responsible for ensuring that the covered functions are performed correctly in accordance with industry rules, firm protocols, policies and procedures by virtue of their position.[56] FINRA stated that it believes this concept, as introduced by FINRA in the Notice to elaborate generally on the role of covered persons, is implicit in each of the three categories of covered persons in proposed Rule 1230(b)(6)(A)(i) through (iii).[57]

One commenter requests that proposed Rule 1230(b)(6)(A)(iii) (''[p]ersons with the authority or discretion materially to commit a member's capital in direct furtherance of the covered functions or to commit a

[38] *Id.*

[39] T–C Services—1.

[40] Response Letter.

[41] *Id.*

[42] *Id.*

[43] SIFMA.

[44] SIFMA.

[45] T–C Services—1.

[46] T–C Services—1.

[47] T–C Services—1.

[48] T–C Services—2 (referencing remarks made by Richard Ketchum, Chairman and CEO of FINRA).

[49] Response Letter.

[50] *Id.*

[51] *See also* proposed FINRA Rule 1230.06 (Scope of Operations Professional Requirement) (excluding from registration those persons whose activities are limited to performing a function ancillary to a covered function, or whose function is to serve a role that can be viewed as supportive of or advisory to the performance of a covered function).

[52] WFA.

[53] WFA.

[54] Response Letter.

[55] *Id.*

[56] *Id.*

[57] *Id.*

member to any material contract or agreement (written or oral) in direct furtherance of the covered functions'') be amended to state that only written contracts are within its scope to avoid confusion arising from interpreting when an oral contract may arise in the context of back-office operations.[58] FINRA stated that it does not intend to amend the proposal as suggested by the commenter.[59] FINRA said the parenthetical language that makes express that both written and oral contracts are included in the proposed rule derives from NYSE Rule 345.10 in the definition of a ''securities lending representative.''[60] FINRA stated that it believes that any contract or agreement, written or oral, that materially commits a member in direct furtherance of the covered functions (not just in the context of a securities lending arrangement) is of a nature requiring the registration of the person making such commitment on behalf of the member.[61]

One commenter requests clarification regarding the statement in the Notice which provides ''covered functions generally would not include a person who engages in administrative responsibilities, such as an initial drafter or code developer. A person who supervises or approves such activities, however, generally would be required to register as an Operations Professional.''[62] The commenter believes this statement runs counter to the proposed supplementary material excluding ancillary functions to a covered function since such supervisor or approver may not have primary responsibility for a covered function.[63] FINRA notes that the proposed rule change does not require primary responsibility for a covered function to trigger registration.[64] FINRA stated that a person who signs off on and/or supervises the activities or personnel involved in writing code to implement firm systems and business requirements is not performing a function that is ancillary to a covered function because their responsibility has a direct nexus to the execution of an activity covered by the proposed rule at a supervisory level.[65]

One commenter requests FINRA acknowledge that firms tailor their supervisory and supervisory control procedures to reflect their business size and organizational structure, and that as a result, the hierarchy of supervisors registered as Operations Professionals will vary depending on a particular firm's system of supervision and the particular covered function.[66] Additionally, the commenter requests FINRA acknowledge it is not a presumption that all ''managers'' with direct reports engaged in covered functions be registered if the responsibility for supervision of the activity, as contemplated by NASD Rule 3010, resides at a higher level of the organization.[67]

FINRA stated that it believes the comment regarding firm supervisory and supervisory control procedures is outside the scope of the proposed rule change.[68] FINRA noted that the proposed rule does not include a requirement regarding a firm's supervisory and supervisory control procedures.[69] FINRA stated that members are responsible for ensuring that any person who meets the requirements to register as an Operations Professional is appropriately registered, regardless of the firm's particular supervisory and supervisory control procedures.[70] Additionally, FINRA stated that the proposed rule change creates a function-based registration requirement, so members must examine the activities of their operations personnel to determine who would be required to register.[71] FINRA said it will not make categorical exclusions based on a person's title or department.[72]

B. Covered Functions

FINRA's proposed rule would require a person to register as an Operations Professional if the person is a ''covered person'' (discussed in Part A above) with responsibility for one or more of 16 ''covered functions.'' Proposed Rule 1230(b)(6)(B) defines covered functions as: (i) Client on-boarding (customer account data and document maintenance); (ii) collection, maintenance, re-investment (*i.e.,* sweeps) and disbursement of funds; (iii) receipt and delivery of securities and funds, account transfers; (iv) bank, custody, depository and firm account management and reconciliation; (v) settlement, fail control, buy ins, segregation, possession and control; (vi) trade confirmation and account statements; (vii) margin; (viii) stock loan/securities lending; (ix) prime brokerage (services to other broker-dealers and financial institutions); (x) approval of pricing models used for valuations; (xi) financial control, including general ledger and treasury; (xii) contributing to the process of preparing and filing financial regulatory reports; (xiii) defining and approving business requirements for sales and trading systems and any other systems related to the covered functions, and validation that these systems meet such business requirements; (xiv) defining and approving business security requirements and policies for information technology, including, but not limited to, systems and data, in connection with the covered functions; (xv) defining and approving information entitlement policies in connection with the covered functions; and (xvi) posting entries to a member's books and records in connection with the covered functions to ensure integrity and compliance with the Federal securities laws and regulations and FINRA rules.

One commenter urges the SEC to direct FINRA to revise the proposed rule to remove and/or clarify certain covered functions not necessary to achieve the stated objectives of the rule.[73] Another commenter finds certain covered functions unclear and notes firms will incur unnecessary costs by broadly interpreting the covered functions to include activities not intended to be covered by the proposed rule.[74] Another commenter believes the proposed rule change may cause confusion with the use of the term ''operations'' since the proposed rule spans many different areas of a firm's business and is not limited to ''trading and operations,'' which is a distinct area of a firm handling clearing, daily disbursements and account activity.[75] One commenter requests clarification that the covered functions do not cover ''client-facing'' or ''front-office'' personnel who may have some involvement in a covered function (*e.g.,* with respect to ''client on-boarding'' in proposed Rule 1230(b)(6)(B)(i), the activities of unregistered employees who assist in gathering new account forms/documentation and information from customers as part of clerical or administrative duties).[76] The commenter requests this clarification

[58] SIFMA.
[59] Response Letter.
[60] *Id.*
[61] *Id.*
[62] T–C Services—1.
[63] T–C Services—1.
[64] Response Letter.
[65] *Id.*
[66] SIFMA.
[67] SIFMA.
[68] Response Letter.
[69] *Id.*
[70] *Id.*
[71] *Id.*
[72] *Id.*
[73] NSCP.
[74] TLG.
[75] NPH.
[76] SIFMA.

with respect to the other covered functions as well.[77]

FINRA notes that the proposed rule change would affect personnel who meet the depth of personnel in proposed Rule 1230(b)(6)(A) and are engaged in one or more covered functions in proposed Rule 1230(b)(6)(B), and does not distinguish on the basis of whether such persons are ''client-facing'' or ''front-office'' personnel.[78] FINRA notes, however, that an unregistered employee who gathers documentation and information in a purely clerical or ministerial capacity likely would not be required to register as an Operations Professional based on the supplementary material in proposed Rule 1230.06.[79]

One commenter requests guidance regarding the term ''client on-boarding'' in proposed Rule 1230(b)(6)(B)(i) because certain terms commonplace in a general securities business broker-dealer practice are not readily transferable to variable annuity sales, and firms should not be faced with the risk of non-compliance due to unclear rule text.[80] The commenter suggests it may be helpful to link each covered function to FINRA or SEC customer account and recordkeeping rules, similar to the text in proposed Rule 1230(b)(6)(B)(xvi).[81] FINRA declines to amend the proposed rule change to link each of the covered functions to relevant FINRA or SEC rules as it is the responsibility of members to determine the regulatory requirements applicable to the firms' operations based on their activities.[82] FINRA notes that client on-boarding would include, but is not limited to, account management activities such as customer account initiation and maintenance, related party account information and maintenance, maintaining client terms and conditions and maintaining contact information.[83] FINRA reminded members to view the covered functions in the context of the depth of personnel in proposed Rule 1230(b)(6)(A).[84]

One commenter suggests the covered functions be revised to identify specific functions, responsibilities or activities related to the covered functions (*e.g.,* the covered function ''[t]rade confirmation and account statements'' (proposed Rule 1230(b)(6)(B)(vi)) fails to provide guidance on what functions, responsibilities or activities related to the compilation and/or production of account statements would require registration).[85] The commenter notes that many brokerage accounts include cash management features (*e.g.,* linked accounts, online bill pay and payroll check deposit), which are provided via agreements with other financial institutions, and transactional information related to these cash management services is included in the brokerage account statements. The commenter notes that the proposed rule would appear to require the member to register not only the associated persons of the member firm but also the supervisors, managers and others employed by non-member financial institutions.[86] Additionally, the commenter points out that broker-dealers use exchanges and third-party service providers for pricing and valuations under proposed Rule 1230(b)(6)(B)(x) (''[a]pproval of pricing models used for valuations'') and believes that the entire management chain of command at the exchanges or third-party service providers may be required to register as an Operations Professional with the member.[87]

FINRA stated that it views covered persons engaging in one or more of the covered functions on behalf of the member to be associated persons of the member, irrespective of their employing entity, and the proposed rule would require such persons to be registered with FINRA as an Operations Professional.[88] However, FINRA recognizes the distinction between shared services models and arrangements in which another financial institution provides distinct cash management services in connection with a brokerage account.[89] In the latter situation, FINRA states that it would not view the financial institution's employees to be associated persons of the member.[90] Moreover, with respect to proposed Rule 1230(b)(6)(B)(x), FINRA recognizes that certain data elements may be purchased by a member as part of its execution of certain covered functions, and would not view employees of such providers of data elements to be associated persons of the member based solely on these activities; however, FINRA notes that the proposed rule does not speak to the propriety of relying on one or more data elements provided by third parties.[91]

One commenter requests that FINRA delete the parenthetical language in FINRA Rule 1230(b)(6)(B)(ix) (''[p]rime brokerage (services to other broker-dealers and financial institutions)'') because the term ''prime brokerage'' is well understood in the industry and the term ''financial institutions'' creates ambiguity since it is not defined in the proposed rule.[92] The commenter also recommends modifying proposed Rule 1230(b)(6)(B)(x) (''[a]pproval of pricing models used for valuations'') to ''approval of pricing models used for the valuation of customer holdings'' since, as proposed, it may sweep in firm risk management or credit functions, which the commenter believes are outside the intent of the proposed rule change.[93] FINRA stated that it does not intend to amend these provisions and notes that the commenter did not provide details regarding the perceived ambiguity in proposed Rule 1230(b)(6)(B)(ix).[94] With respect to the commenter's concerns with proposed Rule 1230(b)(6)(B)(x), FINRA does not intend to regulate risk management practices of firms through the proposed rule.[95] FINRA stated that nothing in the proposed rule is meant to reach the risk management function of modeling used by firms to calculate capital, margin or liquidity requirements.[96] However, FINRA notes that this provision is not limited to valuations of customer holdings and would include firm holdings of inventory positions.[97]

Three commenters suggest FINRA refine proposed Rule 1230(b)(6)(B)(xii) (''[c]ontributing to the process of preparing and filing financial regulatory reports'') because the phrase ''contributing to the process of'' is overly broad, interjects unnecessary uncertainty as to who qualifies as a covered person and is inconsistent with the depth of staff concept in subparagraph (A) of the proposed rule.[98] One commenter recommends refining this provision to focus more on the development, creation and maintenance of financial regulatory reports.[99] Another commenter notes that as proposed the function may capture numerous areas that merely provide a support function, including IT, legal and compliance and any area of a

[77] SIFMA.
[78] Response Letter.
[79] *Id.*
[80] Sutherland.
[81] Sutherland.
[82] Response Letter.
[83] *Id.*
[84] *Id.*
[85] Schwab.
[86] Schwab.
[87] Schwab.
[88] Response Letter.
[89] *Id.*
[90] *Id.*
[91] Response Letter.
[92] SIFMA.
[93] SIFMA.
[94] Response Letter.
[95] *Id.*
[96] *Id.*
[97] Response Letter.
[98] SIFMA, T–C Services—1 and WFA.
[99] WFA.

member firm that provides information included in the report.[100]

FINRA stated that it does not intend to amend proposed Rule 1230(b)(6)(B)(xii) because it believes this provision captures the appropriate spectrum of personnel as proposed.[101] FINRA also reiterates that only persons who are both covered persons and conduct activities or functions in one or more of the covered functions would be subject to the new Operations Professional registration category, and that proposed FINRA Rule 1230.06 specifically excludes persons whose activities are limited to performing a function ancillary to a covered function, or whose function is to serve a role that can be viewed as supportive of or advisory to the performance of a covered function (*e.g.,* internal audit, legal or compliance personnel who review but do not have primary responsibility for any covered function), or who engages solely in clerical or ministerial activities in a covered function.[102]

One commenter urges FINRA to refine the scope and application of proposed FINRA Rule 1230(b)(6)(B)(xiv) (''[d]efining and approving business security requirements and policies for information technology, including, but not limited to, systems and data, in connection with the covered functions'') because it could sweep in virtually all individuals who work in a firm's IT department.[103] Another commenter suggests the covered functions in proposed FINRA Rule 1230(b)(6)(B)(xiii), (xiv), and (xv) should specifically exclude persons executing technical requirements defined and approved by individuals who are supervised by one or more Operations Professionals since, as currently drafted, the proposed rule could sweep in senior management and other supervisors and managers in the IT and IS departments that merely execute the instructions of an area appropriately staffed by an Operations Professional chain of command.[104] One commenter notes that the covered functions in proposed FINRA Rule 1230(b)(6)(B)(xiii) through (xv) are extraneous because personnel in technology do not define and approve business requirements or define and approve business security requirements autonomously without oversight and approval from personnel in the covered functions for which the systems are being designed, and any technology personnel working directly in a covered function would be subsumed by such covered function and do not require a separate provision.[105] The commenter believes that subparagraphs (xiii) through (xv) are ambiguously worded and confusing, and suggests consolidating the technology covered functions into one function as follows: ''information technology (including information security) supporting the other covered functions in paragraph (b)(6)(B) of this Rule.'' [106] The commenter suggests supplementary material to the proposed rule to exclude junior technical experts leading a project team from registration as an Operations Professional.[107] The commenter also requests a grace period for passing the examination for technology managers who move into a position requiring registration given that they move from area to area in a large firm and it may be disruptive to firms.[108]

Two commenters request clarification that the proposed rule applies only to those who sign off on requirements and perform testing to validate systems rather than those who build and implement the systems because a broader application of the rule would create significant challenges to the reallocation of technology resources as projects emerge across firms and could lead to challenges in recruiting technology professionals to work in the securities industry.[109] One commenter requests that FINRA clarify language in the rule filing that may conflict with the proposed rule text in proposed Rule 1230(b)(6)(B)(xiii) because it creates ambiguity by suggesting that supervisors of IT development teams that do not define, approve or validate systems may have to register as an Operations Professional, while the proposed rule does not require it.[110]

FINRA stated that it does not intend to make the suggested changes to proposed Rule 1230(b)(6)(B)(xiii) through (xv) as suggested by the commenters because it believes these provisions are clear as proposed.[111] FINRA notes that comments asserting that a covered function could sweep an entire IT department into the proposed registration category for Operations Professionals fail to consider the covered functions in the context of the depth of personnel set forth in proposed Rule 1230(b)(6)(A).[112] FINRA stated that it does not agree that an entire IT or IS department is likely to meet such a threshold. Member firms are responsible for determining the personnel in IT and IS departments that are engaged in the covered functions at the depth of personnel set forth in proposed Rule 1230(b)(6)(A).

One commenter requests that FINRA revise the language in proposed Rule 1230(b)(6)(B)(xvi) (''[p]osting entries to a member's books and records in connection with the covered functions to ensure integrity and compliance with the Federal securities laws and regulations and FINRA rules'') to distinguish that only those who define that process, determine how the work is performed and approve the entries be required to register under this provision, akin to the covered functions in proposed Rule 1230(b)(6)(B)(xiii) and (xiv).[113] One commenter recommends deleting proposed Rule 1230(b)(6)(B)(xvi) as redundant because part of the obligation of those performing the covered functions in subparagraphs (i) through (xv) is to comply with the regulatory requirements regarding books and records related to such covered functions.[114]

FINRA stated that it views the covered function relating to a member's books and records in proposed Rule 1230(b)(6)(B)(xvi) as clearly distinguishable from the IT functions in proposed Rule 1230(b)(6)(B)(xiii) and (xiv), so does not intend to amend the proposed rule as recommended by the commenter.[115] FINRA explains that it is addressing covered persons who define and approve IT systems in one context and covered persons responsible for the function of posting entries to the member's books and records in the other.[116] Additionally, FINRA states that it believes that the covered function in proposed Rule 1230(b)(6)(B)(xvi) is necessary to make clear that covered persons responsible for books and records posting activities in connection with the covered functions are subject to the proposed requirements.[117]

[100] T–C Services—1.

[101] Response Letter.

[102] Response Letter.

[103] FSI.

[104] T–C Services—1.

[105] Goldman.

[106] Goldman.

[107] Goldman.

[108] Goldman.

[109] Edward Jones and SIFMA.

[110] SIFMA. The Proposing Release noted that ''the covered functions generally would not include a person who engages in administrative responsibilities, such as an initial drafter or a code developer'' but ''a person who supervises or approves such activities generally would be required to register as an Operations Professional.''

[111] Response Letter.

[112] *Id.*

[113] WFA.

[114] SIFMA.

[115] Response Letter.

[116] *Id.*

[117] *Id.*

C. Extraterritorial Application of the Proposed Rule

One commenter believes the proposed rule change imposes an extraterritorial application of U.S. laws.[118] The commenter suggests that the proposed rule raises serious issues under the U.S. Supreme Court's decision in *Morrison* v. *National Australia Bank Ltd.,* 130 S. Ct. 2869 (2010) and its holding, according to the commenter, that the Exchange Act should be applied extraterritorially only when explicitly authorized by statute. The commenter posits that there is no plain wording in Exchange Act Section 15A(b)(6) allowing extraterritorial application of the proposed rule change to Canada or elsewhere. The commenter notes that Section 30(b) of the Exchange Act provides that the Exchange Act does not apply ''to any person insofar as he transacts a business in securities without the jurisdiction of the United States,'' unless he does so in violation of regulations promulgated by the SEC ''to prevent the evasion of [the Act].''

In addition, the commenter believes the proposed rule conflicts with Exchange Act Rule 15a–6, which, according to the commenter, specifically declines to authorize extraterritorial reach by providing exemptions to certain foreign broker-dealers. The commenter believes the proposed rule change would effectively undermine key exemptions provided by Rule 15a–6 that are extensively relied upon by the international financial services community and could have implications with respect to whether foreign locations are deemed branch offices of a member. The commenter states that the proposed rule would require registration of employees of foreign broker-dealers that are exempt from registration as a U.S. broker-dealer under Rule 15a–6.[119] The commenter states ''Canadian employees performing covered functions involving transactions in securities on a Canadian exchange for registered U.S. broker-dealer affiliates would therefore be subject to all FINRA rules, even though their own Canadian employers are exempt from registration as broker-dealers in the U.S., in accordance with SEC Rule 15a–6.'' The commenter notes that implicit in the Rule 15a–6 broker-to-broker exemption[120] is the determination that the U.S. broker-dealer will carefully select its foreign counterparts and supervise their performance as it is the U.S. broker-dealer's responsibility for execution, clearance and settlement to its U.S. customers, even when transactions are executed abroad.

The commenter also declares that the proposed rule change would violate the obligations of the U.S. under the North American Free Trade Agreement (''NAFTA'') because it would assert extraterritorial reach over cross-border financial activities that were allowed by the SEC at the time the U.S. became a party to NAFTA, and which have since been permitted by the SEC without registration of foreign personnel.[121] The commenter notes that because FINRA's rulemaking power derives from the SEC, its authority can extend no further than that of the SEC. Additionally, the commenter states that FINRA has issued examination deficiencies as if the proposed rule has already been approved and urges the SEC to disapprove the proposed rule change and to take immediate action to cease what it believes is FINRA's de facto enforcement of the proposed requirements. Lastly, the commenter notes that FINRA has failed to consider reasonable alternatives such as evaluating the adequacy of the Canadian regulatory scheme to achieve the regulatory objectives of the proposal and encourages regulatory cooperation in lieu of imposing potentially duplicative requirements.[122]

The commenter's concerns stem from clearing arrangements between a U.S. registered broker-dealer and Canadian firms operating under an exemption from broker-dealer registration in Exchange Act Rule 15a–6(a)(4)(i), in which the Canadian firms clear securities transactions in foreign securities for U.S. institutional investors. FINRA stated that it believes that the commenter's statements with respect to the proposed rule change make certain assumptions that are not requirements imposed by the proposal.[123] FINRA stated that the proposed rule change does not aim to expand the jurisdiction of FINRA, diverge from Federal law, rules or regulations, U.S. Supreme Court precedent or violate the obligations of the U.S. under NAFTA.[124] FINRA notes that it is a membership organization with jurisdiction over FINRA members and their associated persons by virtue of its By-Laws and membership agreements.[125] FINRA stated that, without opining on the extraterritorial application of U.S. securities laws, it questions the relevance of the *Morrison* decision, which addressed the extraterritorial application of Section 10(b) of the Exchange Act and Exchange Act Rule 10b–5, and the obligations of the U.S. under NAFTA, to the proposed rule change.[126] FINRA stated that the proposed rule change addresses the obligations of members under FINRA rules with respect to the registration and qualification of certain associated persons who are engaged in, responsible for or supervising certain member operations functions.[127] As noted above, FINRA stated that its jurisdiction reaches associated persons of members and their activities, regardless of their employing entity.[128] The Commission agrees with FINRA that the proposed rule does not expand FINRA's jurisdiction. Furthermore, FINRA stated that it is not within its purview to interpret the Federal securities laws or SEC rules.[129]

Additionally, FINRA disagrees with the commenter's assessment of an implied application of a proposed FINRA rule.[130] As stated by the commenter,[131] and without independent verification or comment, FINRA noted that the examination findings cited by the commenter relate to the firm's outsourcing arrangements and compliance with Exchange Act Rule 15c3–3(k)(2)(i), and the comment is outside the scope of the proposed rule change.[132]

D. Examination Requirement

One commenter states that an examination requirement provides no benefit to investors and FINRA is the

[118] A&P.

[119] A&P.

[120] The commenter represents firms operating under an exemption in Exchange Act Rule 15a–6(a)(4)(i), 17 CFR 240.15a–6(a)(4)(i), known as the broker-to-broker exemption, which provides ''[a] foreign broker or dealer shall be exempt from the registration requirements of sections 15(a)(1) or 15B(a)(1) of the Act to the extent that the foreign broker or dealer effects transactions in securities with or for, or induces or attempts to induce the purchase or sale of any security by a registered broker or dealer, whether the registered broker or dealer is acting as principal for its own account or as agent for others, or a bank acting pursuant to an exception or exemption from the definition of broker or dealer in sections 3(a)(4)(B), 3(a)(4)(E) or 3(a)(5)(C) of the Act.''

[121] The commenter asserts that Article 1404(1) of NAFTA prohibits the U.S. from adopting any measure restricting any type of cross-border trade in financial services by cross-border financial services providers of another Party that the Party permits on the date of entry into force of NAFTA, except as provided in Section B of the Party's Schedule to Annex VII. Under Section B, the U.S. reserves the right to adopt any measure relating to cross-border trade in securities services that derogates from Article 1404(1).

[122] A&P.

[123] Response Letter.

[124] *Id.*

[125] *Id.*

[126] *Id.*

[127] *Id.*

[128] *Id.*

[129] *Id.*

[130] *Id.*

[131] A&P, at note 1.

[132] Response Letter.

true winner as it collects fees for testing, continuing education and other potential items it will generate.[133] Another commenter asserts that a qualification examination is unnecessary to meet the objectives of the proposal and recommends using firm written supervisory procedures and Firm Element training.[134] Two commenters state FINRA should carefully evaluate the objectives and consequences of a one-size-fits-all examination requirement on potential test takers and recommend internal firm element training to deliver the proposed product, market and operations knowledge portion of the required examination content.[135] One commenter supports the original intent of the examination requirement, which was to establish a ''spot-the-red-flags'' examination that would train test takers to identify and escalate potential control problems, and believes that the scope should not be expanded to cover the details of different products, operations processes and rules and regulations given the breadth of the covered functions.[136] Further, the commenter notes that a high failure rate will cause operational disruption at firms.[137] One commenter notes that the examination will be overbroad and extremely challenging for many test takers, especially IT personnel who serve across the covered functions who may have particular difficulty given their minimal background or experience in industry issues.[138]

FINRA stated that it believes that the proposed qualification examination requirement for Operations Professionals is appropriate as proposed and does not agree that the objectives of the proposal can be attained without a testing requirement for unregistered personnel.[139] As FINRA noted in the Notice, it believes there is value in an examination that tests for general securities knowledge about the securities industry and that ongoing continuing education will supplement this knowledge for Operations Professionals.[140] FINRA stated that the draft content outline for the proposed Operations Professional examination was developed by FINRA staff in conjunction with industry subject matter expert volunteers.[141] FINRA stated that its staff conducted several focus panels in mid-2010 with operations professionals working in one or more of the covered functions and from a wide range of FINRA member firms.[142] FINRA said that it then convened an Operations Professional exam committee consisting of more than 40 operations professionals; such persons represent a broad range of FINRA members, including size, geographical location and business model.[143] FINRA stated that both FINRA staff and committee members placed an emphasis on creating a content outline and questions that are appropriate across all the covered functions and test the appropriate level of knowledge for a person who meets the depth of personnel as an Operations Professional.[144]

E. Exception to Qualification Examination Requirement

FINRA noted that the proposed rule change would include an exception to the Operations Professional qualification examination requirement for persons who currently hold certain registrations (each an ''eligible registration'') or have held one during the two years immediately prior to registering as an Operations Professional.[145] FINRA stated that the proposed exception also would apply to persons who do not hold an eligible registration, but prefer an alternative to taking the Operations Professional examination.[146] FINRA said such persons would be permitted to register in an eligible registration category (subject to passing the corresponding qualification examination or obtaining a waiver) and use such registration to qualify for Operations Professional registration.[147]

One commenter questions the value of an additional registration category with such a broad exception since the majority of individuals that would be subject to the proposed rule change would be eligible for the proposed exception.[148] To provide a clearer indication that the proposed rule change is necessary, the commenter recommends FINRA engage in an industry-wide survey to determine how many individuals would not qualify for the exception.[149] Two commenters assert that the proposed exception is overly broad and will undermine the regulatory purpose of the proposal.[150] One such commenter believes content overlap of the eligible registration qualification examinations with the proposed Operations Professional examination is not sufficient justification to accept one examination in lieu of another and finds it inappropriate to grant a waiver to an individual who has passed certain examinations that are limited in nature (*e.g.,* Series 6).[151]

One commenter recommends exempting persons who qualify for the proposed exception from the requirement to separately register as an Operations Professional (noting that costs to make internal system changes to track and monitor dual registrations may be significant), since FINRA's stated goal is to ensure that covered persons are registered with FINRA and trained on industry practices.[152] Another commenter suggests FINRA specifically exempt supervisory personnel who hold the most senior supervisory qualifications (*i.e.,* Series 24 and Series 27) from the requirement to register as an Operations Professional based on the same policy reasoning for exempting certain licensed individuals from the examination requirement.[153] Another commenter recommends FINRA include as an eligible registration the UK FSA-approved Securities & Investment Level 3 Investment Operations Certificate (IOC) and the Investment Administration Qualification (IAQ), both widely recognized within the financial services industry in the UK.[154]

Given the significant functions performed by Operations Professionals, FINRA stated that it believes a separate registration category for such personnel is an appropriate measure to enhance the operational integrity of members.[155] FINRA stated that, as noted in the Notice, a primary purpose of the proposed qualification examination is to assess a covered person's basic understanding of the securities industry and the requirement to take a registration examination serves to alert such person of the role he or she plays

[133] Callaway.

[134] FSI.

[135] NSCP and TLG.

[136] SIFMA.

[137] SIFMA.

[138] NSCP.

[139] Response Letter.

[140] FINRA notes that NASD Rule 1070 (Qualification Examinations and Waiver of Requirements), as well as other applicable provisions regarding registration and qualification set forth in FINRA's rulebook, such as NASD Rule 1031(c) regarding requirements for examination on lapse of registration, would apply to the Operations Professional qualification examination and registration category.

[141] Response Letter.

[142] *Id.*

[143] *Id.*

[144] *Id.*

[145] *Id.*

[146] *Id.*

[147] Response Letter.

[148] NPH.

[149] NPH.

[150] NASAA and NPH.

[151] NASAA.

[152] NMIS.

[153] Goldman.

[154] SIFMA.

[155] Response Letter.

in this highly regulated environment.[156] Thus, FINRA believes the eligible registrations (and corresponding examinations) serve as a valid proxy for the Operations Professional examination requirement.[157] In addition, FINRA is proposing to add language to proposed Rule 1230(b)(6)(D) to provide that FINRA staff may accept as an alternative to the Operations Professional qualification examination requirement any domestic or foreign qualification if it determines that acceptance of such alternative qualification is consistent with the purposes of the rule, the protection of investors, and the public interest.[158]

FINRA stated that the proposed exception applies to the Operations Professional examination requirement only and not Firm Element training.[159] FINRA noted that individuals who avail themselves of the proposed exception to the Operations Professional examination requirement with an eligible registration would be subject to the Regulatory Element program appropriate for such other registration category; however, Operations Professionals would be subject to Firm Element training based on their activities at the firm, which would include the activities in the covered functions that mandate their registration as an Operations Professional.[160]

F. Implementation Period and Grace Period for Non-Clearing Firms

FINRA stated that in *Regulatory Notice* 10–25, it proposed a six- to nine-month transition period for the proposed rule change.[161] In the Notice, FINRA proposed to a 60-day identification period beginning on the effective date of the proposed rule change during which persons required to register as an Operations Professional as of the effective date of the proposed rule change (''Day-One Professionals'') must request registration as an Operations Professional via Form U4 in CRD. Day-One Professionals who are identified during the 60-day period and must pass the Operations Professional examination (or an eligible qualification examination) to qualify would be granted 12 months beginning on the effective date of the proposed rule change to pass such qualifying examination, during which time such persons may function as an Operations Professional. The 12-month transition period to pass a qualification examination would only apply to Day-One Professionals so any person who is not subject to the registration requirements for Operations Professionals as of the effective date of the proposed rule change (''non-Day-One Professionals'') would be required to register as an Operations Professional and, if applicable, pass the Operations Professional qualification examination (or an eligible qualification examination), prior to engaging in any activities that would require such registration. However, any non-Day-One Professional associated with a non-clearing member who must pass the Operations Professional qualification examination (or an eligible qualification examination) to obtain registration would be granted a grace period of 120 days beginning on the date such person requests Operations Professional registration to pass such qualifying examination, during which time such person may function as an Operations Professional.

One commenter believes the proposed implementation period would place an undue burden on the industry and may cause serious disruptions as firms reallocate employee time and resources away from other critical areas.[162] The commenter suggests a three-month identification period followed by a 12-month period for such employees to pass a qualification examination, since the potential burdens and risks of the proposed timeframe far outweigh the minor benefit of the rule being fully effective a few months earlier.[163] Another commenter recommends non-Day-One Professionals, regardless of when they become subject to the proposed registration requirements, be eligible for the 12-month transition period to pass a qualifying examination.[164]

FINRA stated that it does not intend to further extend the proposed implementation period as it believes that the proposed implementation period provides adequate time for members to comply with the proposed rule change.[165] FINRA noted that *Regulatory Notice* 10–25 was published for comment in May 2010, and that the proposed rule change was filed in March 2011.[166] FINRA stated that members have been aware of the proposed rule change for over a year.[167] FINRA stated that it will announce an effective date for the proposed rule change in a *Regulatory Notice* following Commission approval and firms will have 60 days following the effective date of the rule change to identify Day-One Professionals, in addition to the 12-month transition period for those Day-One Professionals who must pass a qualification examination.[168]

One commenter suggests FINRA provide firms with the ability to upload a ''batch'' file of Form U4 registration requests to the CRD system at the conclusion of the initial identification period for Day-One Professionals, since the requirement to maintain dual registrations for such individuals will be administratively complex.[169] FINRA believes that the current Web-based Electronic File Transfer functionality (Web EFT) will enable subscribers to efficiently batch file uploads to Web CRD following approval of the proposed rule change by the Commission.[170]

Numerous commenters suggest extending the 120-day grace period for non-Day-One Professionals associated with a non-clearing member to persons associated with a clearing member firm because similar disruptions to firm operations and client services also may occur at clearing members.[171] Certain commenters believe that if an extension is granted, such individuals should report to a registered Operations Professional or another registered person during the 120-day grace period.[172] One commenter maintains that limiting the 120-day grace period to non-clearing members will force clearing firms to place potentially inexperienced or unqualified employees in a supervisory role simply because they are Operations Professionals, and notes that FINRA should not expect that clearing firms have additional supervisory staff on standby for each department responsible for a covered function.[173] Another commenter notes that without the grace period, a clearing firm may not be able to hire and train new staff on a timely basis or quickly replace staff in the event of a sudden departure, which may disrupt the member's operations and present a significant business continuity risk.[174] The commenter further asserts that the risk involved in extending the grace period to clearing firms is low given that there will be multiple registered persons in the covered areas, members have

[156] *Id.*
[157] *Id.*
[158] *Id.*
[159] *Id.*
[160] *Id.*
[161] *Id.*
[162] SIFMA.
[163] SIFMA.
[164] NSCP.
[165] Response Letter.
[166] *Id.*
[167] *Id.*
[168] *Id.*
[169] SIFMA.
[170] Response Letter.
[171] Edward Jones, JMS, NSCP, Schwab, SIFMA and WFA.
[172] Edward Jones, SIFMA and WFA.
[173] JMS.
[174] SIFMA.

incentive to hire or promote persons qualified to fill vacancies that would require registration, newly hired or promoted persons will be supervised by a registered person and such persons will not be directly interacting with clients.[175]

Based on the comments, FINRA is proposing to extend the 120-day grace period to pass a qualification examination to non-Day-One Professionals associated with a clearing member firm, since clearing firms may experience similar resource challenges in finding qualified new hires and transitioning staff into roles in the covered functions that would require Operations Professional registration.[176]

G. Coordinate Proposed Rule Change With Other FINRA Rule Proposals

Two commenters recommend FINRA coordinate the proposed rule change with other FINRA rule proposals. One commenter requests parallel implementation of the proposed rule change and the proposed registration rules for a coherent, non-duplicative, understandable framework for registration (including the issuance by FINRA of an integrated, comprehensive Notice addressing the comments received on both proposals) since ad hoc implementation of the new registration categories would cause significant burdens to members.[177] Another commenter requests FINRA extend the action date for the proposed rule change so it coincides with the expiration of the comment period for *Regulatory Notice* 11–14 (Third-Party Service Providers) to allow members to consider these closely related proposals concurrently.[178]

FINRA stated that, while it appreciates the commenters' concerns regarding coordination of related rule changes, it believes that the proposed rule change requiring registration of Operations Professionals can proceed now without overly burdening or confusing members.[179] FINRA believes registration and education requirements for the specified operations personnel are needed to help ensure that investor protection mechanisms are in place for all areas of a member's business that could harm the member, a customer, the integrity of the marketplace or the public.[180] FINRA believes that such enhancements should not be unnecessarily postponed, and that it can work with members in implementing future proposed registration rules and requirements relating to third-party service providers separate and apart from the proposed rule change addressing Operations Professional registration.[181]

H. Rulemaking Process

In the Notice, FINRA stated that additional guidance may be needed following the adoption of the proposed rule change and that it would address interpretive questions as needed, similar to its approach to other regulatory initiatives with wide-ranging and novel impacts.[182] One commenter believes that a delay in providing guidance will create confusion and inconsistencies in compliance with the proposed rule, an increased burden on firms in their efforts to comply and hinder FINRA in meeting the objectives of the proposal by failing to provide a clear framework for the proposed requirements.[183] The commenter requests FINRA provide more information regarding industry consultations that took place during the rulemaking process, as the commenter is concerned that a lack of transparency in the rulemaking process will lead to the disenfranchisement of certain segments of the industry.[184]

FINRA believes that it has provided ongoing guidance with respect to the proposed rule change.[185] FINRA stated that it cannot address every specific interpretive issue that may arise in the rulemaking process but has attempted to provide guidance where necessary to assist members in understanding the proposed rule change.[186] FINRA stated that, as with most significant rule proposals, FINRA engaged the industry in crafting the proposed rule change.[187] FINRA said it consulted with industry groups, its advisory committees and panels with representatives from a cross-section of member firms that provided critical input into the depth of personnel for covered persons, the functions for inclusion in the covered functions in the proposed rule and the content of the proposed Operations Professional qualification examination.[188]

I. Costs

One commenter suggests giving the industry flexible and less burdensome alternatives to a new costly registration requirement so they do not have to increase the costs of doing business, stating that FINRA does not justify why registration is the sole effective and cost-efficient means of accomplishing the objectives of the proposal.[189] FINRA believes the proposed rule change is necessary to help ensure that investor protection mechanisms of the highest level possible are in place in all areas of a member's business that could harm the member, a customer, the integrity of the marketplace or the public.[190] FINRA believes that the proposed registration, qualification examination and continuing education requirements for Operations Professionals will best achieve this result.[191]

III. Commission's Findings

After careful review of the proposed rule change, the comment letters and the FINRA Response Letter, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association.[192] In particular, the Commission finds that the proposed rule change is consistent with Section 15A(b)(6) of the Act,[193] which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.

Although FINRA's registration regime historically has focused on ''front office'' personnel who have contact with customers or are otherwise directly involved in effecting securities transactions, persons who perform ''back office'' functions, such as recordkeeping, trade confirmation, transaction settlement, internal auditing, and securities lending operations[194] are also important to a FINRA member's ability to comply with its responsibilities under the Federal securities laws and regulations, and the rules of FINRA. Given the growing complexity of the industry, and the

[175] SIFMA.

[176] Response Letter.

[177] Sutherland. See *Regulatory Notice* 09–70.

[178] JMS.

[179] Response Letter.

[180] *Id.*

[181] *Id.*

[182] Response Letter.

[183] Sutherland.

[184] Sutherland.

[185] Response Letter.

[186] *Id.*

[187] *Id.*

[188] Response Letter.

[189] WFA.

[190] Response Letter.

[191] *Id.*

[192] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[193] 15 U.S.C. 78*o*–3(b)(6).

[194] We note that Section 984 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010), addresses securities lending by, among other things, giving the Commission express authority to regulate persons that ''effect, accept, or facilitate a transaction involving the loan or borrowing of securities.''

importance of the services provided by the back-office personnel, the Commission believes that FINRA's proposal to license and register Operations Professionals and to require members to provide Operations Professionals with continuing education, as amended by Amendment No. 1, will help to address regulatory gaps in this area.

The Commission believes that FINRA carefully considered all the comments on the proposal and has responded appropriately. FINRA's Amendment No 1 changes the proposed rule change in response to certain requests by commenters to clarify the categories of covered persons, accept certain alternative qualification examinations in lieu of the Operations Professional examination, and to extend the 120-day grace period for registration of non-Day-One Professionals to those who will be associated with a clearing member. FINRA has suitably explained its reasons for declining to amend the proposed rule in response to the remainder of the comments it received.

IV. Accelerated Approval

The Commission finds good cause, pursuant to Section 19(b)(2) of the Exchange Act,[195] for approving the proposed rule change, as modified by Amendment No. 1 thereto, prior to the 30th day after publication of notice of the filing of Amendment No. 1 in the **Federal Register**. The proposed rule change was informed by FINRA's consideration of, and the incorporation of many suggestions made in, extensive comments on FINRA's proposal to require the registration of Operations Professionals, and Amendment No. 1's modifications to the proposed rule change add clarity to the proposed rule and provide additional guidance to members and their associated persons.

Accordingly, the Commission finds that good cause exists to approve the proposal, as modified by Amendment No. 1, on an accelerated basis.

V. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as modified by Amendment No. 1, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2011–013 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2011–013. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for 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 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. 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–FINRA–2011–013 and should be submitted on or before July 13, 2011.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[196] that the proposed rule change (SR–FINRA–2011–013), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[197]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–15450 Filed 6–21–11; 8:45 am]

BILLING CODE 8011–01–P

[195] 15 U.S.C. 78s(b)(2).

[196] 15 U.S.C. 78s(b)(2).

[197] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64686; File No. SR–CHX–2011–07]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Order Approving a Proposed Rule Change To Amend Minor Rule Plan

June 16, 2011.

I. Introduction

On April 20, 2011, the Chicago Stock Exchange, Inc. (''CHX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change amending CHX Article 12, Rule 8 (Minor Rule Plan) (''MRP'') to incorporate additional violations into the MRP, increase the sanctions for certain violations, add censure authority to the MRP, eliminate the Minor Rule Violation Panel, clarify pleading requirements of a Respondent seeking to challenge a sanction by instituting a formal disciplinary proceeding, and make other minor changes. The proposed rule change was published for comment in the **Federal Register** on May 5, 2011.[3] The Commission received no comment letters on the proposed rule change. This order approves the proposed rule change.

II. Description

The Exchange proposed to make additional rules subject to punishment under its MRP. These rules relate to: (1) Failure to notify the Exchange of a request to withdraw capital contribution (Article 3, Rule 6(b)); (2) failure to request Exchange approval of the transfer of equity securities of a participant firm (Article 3, Rule 11); (3) reporting of loans (Article 3, Rule 12); (4) failure to provide the Exchange with information (Article 6, Rule 7); (5) impeding or delaying an Exchange examination, inquiry, or investigation (Article 6, Rule 9); (6) designation of e-mail addresses (Article 3, Rule 13); (7) registration and approval of personnel (Article 6, Rule 2(a)); (8) written supervisory procedures (Article 6, Rule 5(b)); (9) failure to report short positions (Article 7, Rule 9); (10) furnishing of records (Article 11, Rule 1); (11) maintenance of books and records (Article 11, Rule 2); (12) participant

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 64370 (April 29, 2011); 76 FR 25727 (''Notice'').

communications (Article 11, Rule 4); (13) market maker registration and appointment (Article 16, Rule 1); (14) market maker reporting of position information (Article 16, Rule 10); (15) institutional broker registration and appointment (Article 17, Rule 1); (16) reporting of transactions (Article 9, Rule 13); (17) institutional broker obligations for entry of orders into an automated system (Article 17, Rule 3(a)); and (18) institutional broker responsibilities for handling orders within an integrated system (Article 17, Rule 3(b)). The Exchange believes that it will be able to carry out its regulatory responsibility more quickly and efficiently by incorporating these violations into its MRP.

The Exchange also proposed to increase the fine levels for certain violations. The Exchange proposed to increase the maximum fine pursuant to the MRP from $2,500 to $5,000 and to increase the fines in the Fine Schedule in order to better deter violative activity and more closely adhere to the fine schedules of other self-regulatory organizations. For most reporting and recordkeeping rule violations and certain trading rule violations, the recommended fines were increased from $100/$500/$1000 for first, second, and third tier fines, respectively, to $250/$750/$1500. The Exchange also proposed recommended fines of $500/$1000/$2500 for other, more serious trading rule violations (*i.e.,* ones which involve the potential for customer harm), as well as violations of the obligation to establish, maintain, and enforce written supervisory procedures, and to provide information to the Exchange in connection with regulatory inquiries or other matters. The Exchange recommended fines of $1000/$2500/$5000 for the most serious violations contained within the Plan (Trading Ahead). Finally, the Exchange proposed to expand the rolling time period in which violations would result in escalation to the next highest tier from 12 to 24 months, which is consistent with the minor rule plans of other exchanges.

In conjunction with altering the fine levels, the Exchange proposed to add a censure authority to the MRP to provide additional flexibility in imposing sanctions in particular cases. A censure could be used in the initial findings of a violation where the Exchange wants to put the Respondent on notice that certain conduct violates CHX rules or in other circumstances in which a monetary fine is not appropriate or necessary.

The Exchange proposed to eliminate the role of the Minor Rule Violation Panel in issuing sanctions pursuant to the MRP, and to authorize certain members of the Exchange's Market Regulation staff to issue MRP sanctions. Specifically, MRP sanctions would be imposed either by the Exchange's Chief Enforcement Counsel or Chief Regulatory Officer. The Exchange noted that allowing members of its staff to issue MRP fines was consistent with the practice at other exchanges regarding MRPs and was also similar to the method by which formal disciplinary actions are instituted by the CHX under Article 12, Rule 1.[4] The Exchange stated that the proposed change would help to expedite the process of issuing MRP sanctions and would eliminate an inherent source of potential conflicts (or appearance thereof) whenever Participants determine disciplinary sanctions.

The Exchange also proposed to clarify the pleading requirements of a Respondent who seeks to challenge a sanction by instituting a formal disciplinary proceeding. The proposed changes would require a Respondent challenging an MRP sanction to file an answer that meets the standards for an answer under Article 12, Rule 5(b). The proposal would authorize the Secretary of the Exchange (the person to whom such responses are directed) to deny the answer for a failure to meet these standards. Under the proposal, the denial of the answer by the Secretary without leave to amend and refile would be considered the final action of the Exchange, and the MRP fine would become due and payable and/or a censure would be imposed. The Exchange also added language incorporating the requirement of Exchange Act Rule 19d–1 relating to the reporting of Exchange disciplinary actions to the Commission.[5]

Finally, the Exchange proposed to make certain non-substantive, clarifying changes to some of the current rules referenced in the MRP. For example, the filing proposed to clarify that the short sale rule (Article 9, Rule 23) applied to all sell orders and not just those of a proprietary nature.[6] In addition, the filing proposed to make changes to address proper rule cites and/or description of rules. For example, the filing proposed to clarify that an institutional broker's best execution obligations under Article 17, Rule 3 specifically fall under paragraph (d) of such rule. In addition, rather than describing the rule as ''Failure to meet best execution obligations'', the rule will be titled ''Institutional Broker obligations in handling orders (best execution).''

III. Discussion and Commission's Findings

The Commission finds that the proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[7] In particular, the Commission believes that the proposal is consistent with Section 6(b)(5) of the Act,[8] which requires that the rules of an exchange be designed to, among other things, protect investors and the public interest. The Commission also believes that the proposal is consistent with Sections 6(b)(1) and 6(b)(6) of the Act,[9] which require that the rules of an exchange enforce compliance with, and provide appropriate discipline for, violations of Commission and Exchange rules. The Commission notes that because CHX Article 12 provides procedural rights to a person fined under the MRP to contest the fine and permits a hearing on the matter, the Commission believes that the MRP provides a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d)(1) of the Act.[10] Furthermore, the Commission believes that the proposed changes to the MRP should strengthen the Exchange's ability to carry out its oversight and enforcement responsibilities as a self-regulatory organization in cases where full disciplinary proceedings are unsuitable in view of the minor nature of the particular violation. Therefore, the Commission finds that the proposal is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act,

[4] *See, e.g.,* Chicago Board Options Exchange (''CBOE'') Rule 17.50(a), Imposition of Fines for Minor Rule Violations (provides for fines to be issued by ''the Exchange''); BATS Exchange Rule 8.15(a), Imposition of Fines for Minor Violation(s) of Rules, (provides for fines to be issued by ''the Exchange''); International Stock Exchange Rule 1614(a), Imposition of Fines for Minor Rule Violations (provides for fines to be issued by ''the Exchange''). Formal disciplinary actions under CHX Article 12, Rule 1 are authorized by the Exchange's Chief Regulatory Officer.

[5] The Exchange's proposed language is based upon language in the Minor Rule Violation Plan of the CBOE. *See* CBOE Rule 17.50(a).

[6] Currently, the Plan only addresses a Participant's duty to comply with the short sale rule when selling short for its own account (*e.g.,* proprietarily). *See* Article 12, Rule 8(h)(ii)(5).

[7] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78f(b)(1) and 78f(b)(6).

[10] 15 U.S.C. 78f(b)(7) and 78f(d)(1).

as required by Rule 19d–1(c)(2) under the Act,[11] which governs minor rule violation plans.

In approving this proposed rule change, the Commission in no way minimizes the importance of compliance with CHX rules and all other rules subject to the imposition of fines under the MRP. The Commission believes that the violation of any self-regulatory organization's rules, as well as Commission rules, is a serious matter. However, the MRP provides a reasonable means of addressing rule violations that do not rise to the level of requiring formal disciplinary proceedings, while providing greater flexibility in handling certain violations. The Commission expects that CHX will continue to conduct surveillance with due diligence and make a determination based on its findings, on a case-by-case basis, whether a fine of more or less than the recommended amount is appropriate for a violation under the MRP or whether a violation requires formal disciplinary action under CHX Article 12.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act[12] and Rule 19d–1(c)(2) under the Act,[13] that the proposed rule change (SR–CHX–2011–07) be, and hereby is, approved and declared effective.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–15553 Filed 6–21–11; 8:45 am]

BILLING CODE 8011–01–P

[11] 17 CFR 240.19d–1(c)(2).

[12] 15 U.S.C. 78s(b)(2).

[13] 17 CFR 240.19d–1(c)(2).

[14] 17 CFR 200.30–3(a)(12); 17 CFR 200.30–3(a)(44).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64693; File No. SR–NYSEAmex–2011–38]

Self-Regulatory Organizations; NYSE Amex LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 903G To Permit the Exchange To List Flexible Exchange Options on Index and Equity Securities That Are Eligible for Non-FLEX Options Trading, and That Have Non-FLEX Options on Such Index and Equity Securities Listed and Traded on at Least One National Securities Exchange, Even if the Exchange Does Not List Such Non-FLEX Options

June 16, 2011.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b-4 thereunder,[3] notice is hereby given that on June 3, 2011, NYSE Amex LLC (the ''Exchange'' or ''NYSE Amex'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 903G (Terms of FLEX Options) to permit the Exchange to list Flexible Exchange Options (''FLEX Options'') on index and equity securities that are eligible for Non-FLEX Options trading, and that have Non-FLEX Options on such index and equity securities listed and traded on at least one national securities exchange, even if the Exchange does not list such Non-FLEX Options. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Rule 903G (Terms of FLEX Options) to permit trading of FLEX Options series in securities whose Non-FLEX Options are listed and traded on a national securities exchange(s), based on a recently adopted rule change of the Chicago Board Options Exchange (''CBOE'').[4]

Rule 903G currently permits the Exchange to approve and open for trading FLEX Options only after the particular index or equity security has been approved for Non-FLEX Options trading.

The Exchange proposes to adopt a rule change similar to a rule change recently adopted by the CBOE to allow FLEX Equity Options on any security that meets the standards of NYSE Amex Rule 915, and that has Non-FLEX Options on such security listed and traded on at least one options exchange, regardless of whether the Exchange trades such Non-FLEX Options.

Similarly, the CBOE rule change also adopted a provision to allow FLEX Index Options on any index that meets its listing standards. NYSE Amex proposes to adopt a similar provision that would permit FLEX Index Options on any index that meets the standards of Rule 901C, and that has Non-FLEX Options on such index listed and traded on at least one options exchange, even if the Exchange does not list and trade such Non-FLEX Options.

The Exchange also proposes to designate 903G(c)(1) as ''reserved'' because the text in that provision stating that FLEX Equity Option transactions are limited to transactions in options on underlying securities that have been approved by the Exchange in accordance with Rule 915 would no longer be applicable.

As an alternative to the over-the-counter marketplace and other national security exchanges, the Exchange proposes to increase the spectrum of indexes and equity securities that are

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 60585 (August 28, 2009), 74 FR 46257 (September 8, 2009). Unlike CBOE's rule, we have clarified that our proposed rule would only permit the trading of FLEX Options on securities whose Non-Flex Options are listed and traded on at least one options exchange.

eligible for FLEX Options trading on the Exchange, even if the Exchange does not list Non-FLEX Options on such indexes or equity securities. In this regard, the Exchange does not list options on every NMS stock or index that is eligible for options trading, even if permitted to do so according to its listing standards, but recognizes that market participants may want access to options on such indexes and equity securities, in addition to the certainty and safeguards that a regulated and standardized marketplace provides.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[5] in general, and furthers the objectives of Section 6(b)(5) of the Act,[6] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes that its proposal to permit the Exchange to list FLEX Options on indexes and equity securities that are eligible for Non-FLEX Options trading and whose Non-FLEX Options are listed and traded on at least one national securities exchange, even if the Exchange does not list such Non-FLEX Options, would provide market participants with additional means to manage their risk exposures and carry out their investment objectives with listed options. In this regard, the Exchange's proposal would increase competition in the FLEX Options market. In addition, the Exchange's proposal is consistent with investor protection and the public interest in that it is limited to FLEX Options on securities that would be eligible to have, and in fact have, Non-FLEX Options listed and traded on them. The criteria for such underlying securities has been carefully crafted over the years to ensure that only appropriate securities have standardized options listed on them (*e.g.,* securities with sufficient trading volume and shareholders).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[7] and Rule 19b–4(f)(6) thereunder.[8]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[9] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[10] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the Exchange could immediately list FLEX Options on indexes and equity securities that are eligible for non-FLEX Options trading, and that have non-FLEX Options on such index and equity securities listed and traded on at least one national securities exchange, even if the Exchange does not list non-FLEX Options on such indexes and equity securities. In support of the waiver, the Exchange believes that it would benefit the marketplace and the investing public because it would provide market participants with additional means to manage their risk exposures and carry out their investment objectives with listed options.

The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest. In making this determination, the Commission notes that NYSE Amex's proposed rule change is substantially similar to CBOE's FLEX rules, which also permit CBOE to list FLEX options on securities that are eligible for non-FLEX options trading, even if CBOE does not list non-FLEX options on such securities.[11] The Commission notes that the CBOE's proposal was subject to full notice and comment, and the Commission received no comments on CBOE's rule proposal. Further, the Commission notes that NYSE Amex's proposal adds clarification to the rules, noting expressly that its rules would only permit the trading of FLEX Options on securities whose non-FLEX Options are listed and traded on at least one national securities exchange. This provision will help to ensure that adequate exchange requirements are met for trading these products and that the FLEX market will provide an alternative to certain investors that want to customize specified options terms not available in the standardized market. In addition to the factors noted above, the Commission also believes that waiver of the operative delay will allow the NYSE Amex to immediately compete with other exchanges for the trading of such FLEX options, thereby providing investors another venue on which to trade these products. For these reasons, the Commission designates, consistent with the protection of investors and the public interest, that the proposed rule change become operative immediately upon filing.[12]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6). Pursuant to Rule 19b–4(f)(6)(iii) under the Act, the Exchange is required to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission notes that the Exchange has satisfied this requirement.

[9] 17 CFR 240.19b–4(f)(6).

[10] 17 CFR 240.19b–4(f)(6)(iii).

[11] *See supra* note 4.

[12] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

• Send an e-mail to *rule-comments@sec.gov.* Please include File No. SR–NYSEAmex–2011–38 on the subject line.

Paper Comments

• Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NYSEAmex–2011–38. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for 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 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of NYSE Amex. 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 No. SR–NYSEAmex–2011–38 and should be submitted on or before July 13, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Elizabeth M. Murphy,

Secretary.

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[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64690; File No. SR–NYSEArca–2011–17]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Granting Approval of Proposed Rule Change Relating to the Listing and Trading of the Madrona Forward Domestic ETF, Madrona Forward International ETF, and Madrona Forward Global Bond ETF

June 16, 2011.

I. Introduction

On April 13, 2011, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of the Madrona Forward Domestic ETF, Madrona Forward International ETF, and Madrona Forward Global Bond ETF (each a ''Fund,'' and, together, the ''Funds'') under NYSE Arca Equities Rule 8.600. The proposed rule change was published in the **Federal Register** on May 2, 2011.[3] The Commission received no comments on the proposal. This order grants approval of the proposed rule change.

II. Description of the Proposal

The Exchange proposes to list and trade the Shares pursuant to NYSE Arca Equities Rule 8.600. The Shares will be offered by the AdvisorShares Trust (''Trust''), a statutory trust organized under the laws of the State of Delaware and registered with the Commission as an open-end management investment company.[4] The investment advisor for the Funds is AdvisorShares Investments, LLC (''Adviser''). Madrona Funds LLC is the Funds' sub-adviser (''Sub-Adviser'') and provides day-to-day portfolio management of the Funds. Foreside Fund Services, LLC (''Distributor'') is the principal underwriter and distributor of the Funds' Shares. The Bank of New York Mellon Corporation (''Administrator'') serves as administrator, custodian, and transfer agent for the Funds. The Exchange states that neither the Adviser nor the Sub-Adviser is affiliated with a broker-dealer.[5]

With respect to each of the Funds, the Sub-Adviser will employ a forward-looking fundamental investment process when making capital allocation decisions across investment strategies for the Funds. The underlying investment process for the Madrona Forward Domestic ETF and the Madrona Forward International ETF is based on a measure of forecasted earnings and projected growth relative to the price of the equities. The underlying investment process for the Madrona Forward Global Bond ETF is based on fundamental yield curve analysis and a measure of mean reversion for future expected yield curve trajectory. Each Fund will utilize a core investment allocation strategy seeking to replace what the Sub-Adviser's investment committee deems inefficient index methodologies for core investing that are prevalent in the marketplace. The Funds will invest in actively managed, broadly diversified portfolios and differ from most traditional indices in that the proportion, or weighting, of the securities in the Funds are based on forward-looking fundamental analysis rather than only on market capitalization of such securities. Risk management guidelines will be employed to protect against dramatic over- or under-weighting of individual securities, reducing company specific risks.

Madrona Forward Domestic ETF

The investment objective of this Fund is to seek long-term capital appreciation above the capital appreciation of its benchmark, the S&P 500 Index. The Sub-Adviser will seek to achieve the Fund's investment objective primarily by selecting a portfolio of up to 500 of the largest U.S. exchange-traded equity securities.[6] The Sub-Adviser will select the securities for the Fund's portfolio

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 64342 (April 26, 2011), 76 FR 24548 (''Notice'').

[4] The Trust is registered under the Investment Company Act of 1940 (''1940 Act''). On November 30, 2010, the Trust filed with the Commission Form N–1A under the Securities Act of 1933 (15 U.S.C. 77a) and under the 1940 Act relating to the Funds (File Nos. 333–157876 and 811–22110) (''Registration Statement''). The Trust has also filed an Application for an Order under Section 6(c) of the 1940 Act for exemptions from various provisions of the 1940 Act and rules thereunder (File No. 812–13677), dated May 6, 2010 (''Exemptive Application'').

[5] *See* Commentary .06 to NYSE Arca Equities Rule 8.600. The Exchange represents that, in the event (a) the Adviser or Sub-Adviser becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser becomes affiliated with a broker-dealer, such adviser and/or sub-adviser will implement a fire wall with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

[6] The Fund may hold only equity securities traded in the U.S. on registered exchanges and will hold a minimum of 13 equity components.

using a weighted allocation system based on a consensus of analyst estimates of the present value of future expected earnings relative to the share price of each security. The Sub-Adviser's investment committee will meet on a bi-weekly basis to monitor the portfolio and make allocation decisions. The investment committee will use third-party analyst research and a proprietary fundamental process to make allocation decisions and employ guidelines to protect against dramatic over- or under-weighting of individual securities in the Fund's portfolio. The investment committee relies heavily on a stock's price and market cap relative to its future expected earnings in its analysis of individual securities. Changes to the Fund's portfolio will typically occur upon the reporting and analysis of individual securities through the earnings season and rely heavily on a stock's price and market cap relative to the future expected earnings.

The Fund will utilize the following investment process:

Step 1: The Sub-Adviser will use third-party research consisting of analysis of the consensus analyst valuation estimates to drive the proprietary models that derive the present value of future expected earnings relative to the current stock price of each stock.

Step 2: The Sub-Adviser will review the data on a company-by-company basis, and the companies will be put in order from most attractive to least attractive, and the Fund will weigh these companies accordingly.

Step 3: Risk management guidelines will be established to allocate the total percentage invested in each quartile of securities. Thus, each group of up to 125 securities will receive a certain investment percentage within the Sub-Adviser's established guidelines, ensuring no dramatic over-weighting or under-weighting of individual securities.

Step 4: The Fund's portfolio will be consistently monitored when company-specific data is released, and the Sub-Adviser's models will be updated to drive allocation changes.

Madrona Forward International ETF

The investment objective of the this Fund is to seek long-term capital appreciation above the capital appreciation of its international benchmarks, the MSCI EAFE Index, the Fund's primary benchmark, and the BNY Mellon Classic ADR Index, the Fund's secondary benchmark. The Fund will select a portfolio primarily composed of U.S. exchange-listed American Depository Receipts (''ADRs'') from among the largest issuers of Europe, Australasia and the Far East (''EAFE''), and Canada. The Fund's portfolio may also include U.S. exchange-listed equity securities of large-capitalization, non-U.S. issuers that provide exposure to certain markets deemed to be emerging markets. Securities are selected, weighted, and sold based upon the Sub-Adviser's proprietary investment process. The Sub-Adviser's investment committee will meet on a bi-weekly basis to monitor the portfolio and make allocation decisions. The investment committee will use third-party analyst research and a proprietary fundamental process to make allocation decisions. Changes to the Fund's portfolio will typically occur upon the reporting and analysis of individual securities through the earnings season and rely heavily on a security's price and market cap relative to future earnings.

The composition of the Fund's portfolio, on a continual basis, will be subject to the following:

(1) Component stocks, including component stocks underlying ADRs, that, in the aggregate, account for at least 90% of the weight of the portfolio, each shall have a minimum market value of at least $100 million;

(2) Component stocks, including component stocks underlying ADRs, that, in the aggregate, account for at least 70% of the weight of the portfolio, each shall have a minimum global monthly trading volume of 250,000 shares, or minimum global notional volume traded per month of $25,000,000, averaged over the last six months;

(3) A minimum of 20 component stocks, including component stocks underlying ADRs, of which the most heavily weighted component stock shall not exceed 25% of the weight of the portfolio, and the five most heavily weighted component stocks shall not exceed 60% of the weight of the portfolio; and

(4) Each non-U.S. equity security underlying ADRs held by the Fund will be listed and traded on an exchange that has last-sale reporting.

The Fund will utilize the following investment process:

Step 1: The Sub-Adviser will use third-party research consisting of analysis of the consensus analyst valuation estimates to drive the proprietary models that derive the present value of future expected earnings relative to the current stock price of each stock.

Step 2: The Sub-Adviser will review the data on a company-by-company basis, and the companies will be put in order from most attractive to least attractive, and the Fund will weigh these companies accordingly.

Step 3: Risk management guidelines will be established to allocate the total percentage invested in each quartile of securities. Each quartile will receive a certain investment percentage within the Sub-Adviser's established guidelines, ensuring no dramatic over-weighting or under-weighting of individual securities.

Step 4: The Fund's portfolio will be consistently monitored when company specific data is released, and the Sub-Adviser's models will be updated to drive allocation changes.

Madrona Forward Global Bond ETF

The investment of this Fund is to seek investment results that exceed the price and yield performance of its benchmark, the Barclays Capital Aggregate Bond Index. The Sub-Adviser will primarily select a portfolio of fixed income (bond) U.S. exchange-traded funds (''ETFs'') and other U.S. exchange-traded products (''ETPs'' and, together with ETFs, ''Underlying ETPs''), including but not limited to, exchange-traded notes (''ETNs''), exchange-traded currency trusts, and exchange-traded commodity pools.[7] The Fund will invest in indexed Underlying ETPs that will invest in at least 12 distinct global bond classes, including, but not limited to, the following: Mortgage Backed/Agency; Investment Grade U.S. Corporate; Short-Term Treasury; Intermediate-Term Treasury; Long-Term Treasury; Inflation Protected Treasury (TIPS); High-Yield U.S. Corporate; International Treasury; Convertible and Preferred; Emerging Markets; Municipal; International Investment Grade Corporate;

[7] Underlying ETPs include Investment Company Units (as described in NYSE Arca Equities Rule 5.2(j)(3)); Index-Linked Securities (as described in NYSE Arca Equities Rule 5.2(j)(6)); Portfolio Depositary Receipts (as described in NYSE Arca Equities Rule 8.100); Trust Issued Receipts (as described in NYSE Arca Equities Rule 8.200); Commodity-Based Trust Shares (as described in NYSE Arca Equities Rule 8.201); Currency Trust Shares (as described in NYSE Arca Equities Rule 8.202); Commodity Index Trust Shares (as described in NYSE Arca Equities Rule 8.203); Trust Units (as described in NYSE Arca Equities Rule 8.500); Managed Fund Shares (as described in NYSE Arca Equities Rule 8.600); and closed-end funds. The Underlying ETPs will be listed and traded in the U.S. on registered exchanges. The Madrona Forward Global Bond ETF may invest in the securities of Underlying ETPs consistent with the requirements of Section 12(d)(1) of the 1940 Act, or any rule, regulation, or order of the Commission or interpretation thereof. The Fund will only make such investments in conformity with the requirements of Section 817 of the Internal Revenue Code of 1986. The Underlying ETPs in which the Fund may invest will primarily be index-based ETFs that hold substantially all of their assets in securities representing a specific index.

International High Yield; and Build America Bonds. Each major bond category would have a three percent minimum percentage inclusion in the Fund's portfolio.

The Fund will invest in an Underlying ETP for each of the bond classes held in the portfolio. Changes to the Fund's portfolio typically occur upon the reporting and analysis of each bond category's risk assessment.

The Fund will utilize the following investment process:

Step 1: The Sub-Adviser will select an Underlying ETP for each bond category based on expense ratios and institutional strengths of each Underlying ETP provider to ensure efficient internal trading.

Step 2: The Sub-Adviser will use third-party research consisting of analysis of the historical class by class yield-curve analysis and how the curve stands in relation to the current yield-curve of the particular bond class. Based on the research, the Sub-Adviser will determine which bond classes will receive higher- and lower-than-average allocations as compared to typical bond indices.

Step 3: Risk management guidelines will be established to allocate the total percentage invested in each bond class. Each class will receive a minimum investment within the Sub-Adviser's established guidelines, ensuring no dramatic over-weighting or under-weighting of individual bond categories.

Step 4: The Fund's portfolio will be consistently monitored when bond class data is released, and the Sub-Adviser's models will be updated to drive allocation changes.

Other Investments of the Funds

Each Fund may invest 100% of its total assets in short-term, high-quality debt securities and money market instruments either directly or through Underlying ETPs to respond to adverse market, economic, or political conditions.[8] A Fund may invest in such instruments for extended periods, depending on the Sub-Adviser's assessment of market conditions. These debt securities and money market instruments may include shares of other mutual funds, commercial paper, certificates of deposit, bankers' acceptances, U.S. Government securities, repurchase agreements, and bonds that are rated BBB or higher. The Funds also may invest in shares of REITs, which are pooled investment vehicles that invest primarily in real estate or real estate-related loans.

A Fund will not (i) With respect to 75% of its total assets, purchase securities of any issuer (except securities issued or guaranteed by the U.S. Government, its agencies or instrumentalities, or shares of investment companies) if, as a result, more than 5% of its total assets would be invested in the securities of such issuer; or (ii) acquire more than 10% of the outstanding voting securities of any one issuer. For purposes of this policy, the issuer of the underlying security will be deemed to be the issuer of any respective ADR.

A Fund will not invest 25% or more of its total assets in the securities of one or more issuers conducting their principal business activities in the same industry or group of industries. This limitation will not apply to investments in securities issued or guaranteed by the U.S. Government, its agencies or instrumentalities, or shares of investment companies. Each Fund will not invest 25% or more of its total assets in any investment company that so concentrates. For purposes of this policy, the issuer of the underlying security will be deemed to be the issuer of any respective ADR.

The Funds will not purchase illiquid securities if, in the aggregate, more than 15% of their net assets would be invested in illiquid securities. Except for Underlying ETPs that may hold non-U.S. issues, the Funds will not otherwise invest in non-U.S.-registered issues. In addition, the Funds intend to qualify for treatment as a Regulated Investment Company under the Internal Revenue Code.

Pursuant to the terms of the Exemptive Application, the Funds will not invest in options contracts, futures contracts, or swap agreements. The Funds' investments will be consistent with each Fund's investment objective and will not be used to enhance leverage.

Additional information regarding the Trust, the Funds, and the Shares, the Funds' investment strategies, risks, creation and redemption procedures, fees, portfolio holdings and disclosure policies, distributions and taxes, availability of information, trading rules and halts, and surveillance procedures, among other things, can be found in the Notice and the Registration Statement, as applicable.[9]

III. Discussion and Commission's Findings

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of Section 6 of the Act[10] and the rules and regulations thereunder applicable to a national securities exchange.[11] In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[12] which requires, among other things, that the Exchange's rules be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission notes that the Shares must comply with the requirements of NYSE Arca Equities Rule 8.600 to be listed and traded on the Exchange.

The Commission finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Act,[13] which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities. Quotation and last-sale information for the Shares will be available via the Consolidated Tape Association high-speed line. In addition, the Portfolio Indicative Value, as defined in NYSE Arca Equities Rule 8.600(c)(3), will be disseminated by the Exchange at least every 15 seconds during the Core Trading Session. On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Funds will disclose on their Web site the Disclosed Portfolio, as defined in NYSE Arca Equities Rule 8.600(c)(2), that will form the basis for each Fund's calculation of the net asset value (''NAV'') at the end of the business day.[14] The NAV of each of the

[8] Adverse market conditions would include large downturns in the broad market value of two or more times current average volatility, where the Sub-Adviser views such downturns as likely to continue for an extended period of time. Adverse economic conditions would include significant negative results in factors deemed critical at the time by the Sub-Adviser, including significant negative results regarding unemployment, Gross Domestic Product, consumer spending or housing numbers. Adverse political conditions would include events such as government overthrows or instability, where the Sub-Adviser expects that such events may potentially create a negative market or economic condition for an extended period of time.

[9] *See* Notice and Registration Statement, *supra* notes 3 and 4, respectively.

[10] 15 U.S.C. 78f.

[11] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[12] 17 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[14] On a daily basis, the Adviser will disclose for each portfolio security or other financial instrument of the Funds the following information: Ticker symbol (if applicable), name of security or financial

Funds will be determined as of the close of the regular trading session on the New York Stock Exchange (''NYSE'') (ordinarily 4 p.m. Eastern Time) on each business day. The intra-day, closing, and settlement prices of the portfolio securities are readily available from the national securities exchanges trading such securities, automated quotation systems, published or other public sources, or on-line information services such as Bloomberg or Reuters. In addition, a basket composition file, which includes the security names and share quantities required to be delivered in exchange for Fund shares, together with estimates and actual cash components, will be publicly disseminated daily prior to the opening of the NYSE via the National Securities Clearing Corporation. Information regarding market price and trading volume of the Shares is and will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and information regarding the previous day's closing price and trading volume information will be published daily in the financial section of newspapers. The Funds' Web site will also include a form of the prospectus for the Funds, information relating to NAV, and other quantitative and trading information.

The Commission further believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Commission notes that the Exchange will obtain a representation from the issuer of the Shares that the NAV will be calculated daily, and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.[15] In addition, the Exchange will halt trading in the Shares under the specific circumstances set forth in NYSE Arca Equities Rule 8.600(d)(2)(D), and may halt trading in the Shares if trading is not occurring in the securities and/or the financial instruments comprising the Disclosed Portfolio of the Funds, or if other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.[16] Further, the Commission notes that the Reporting Authority that provides the Disclosed Portfolio must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the actual components of the portfolio.[17] The Exchange states that neither the Adviser nor the Sub-Adviser is affiliated with a broker-dealer.[18]

The Exchange represents that the Shares are deemed to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. In support of this proposal, the Exchange has made representations, including:

(1) The Shares will conform to the initial and continued listing criteria under NYSE Arca Equities Rule 8.600.

(2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(3) The Exchange's surveillance procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable Federal securities laws.

(4) Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit (''ETP'') Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (a) The procedures for purchases and redemptions of Shares in Creation Unit aggregations (and that Shares are not individually redeemable); (b) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (c) the risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated Portfolio Indicative Value will not be calculated or publicly disseminated; (d) how information regarding the Portfolio Indicative Value is disseminated; (e) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading and other information.

(5) For initial and/or continued listing, the Funds will be in compliance with Rule 10A–3 under the Act,[19] as provided by NYSE Arca Equities Rule 5.3.

(6) The Funds will not invest in non-U.S. equity securities (except for Underlying ETPs that may hold non-U.S. issues), options contracts, futures contracts, or swap agreements. In addition, the Funds' investments will be consistent with each Fund's investment objective and will not be used to enhance leverage.

(7) A minimum of 100,000 Shares of each Fund will be outstanding at the commencement of trading on the Exchange.

This approval order is based on the Exchange's representations.

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act[20] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[21] that the proposed rule change (SR–NYSEArca–2011–17) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–15608 Filed 6–21–11; 8:45 am]

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instrument, number of shares or dollar value of financial instruments held in the portfolio, and percentage weighting of the security or financial instrument in the portfolio.

[15] *See* NYSE Arca Equities Rule 8.600(d)(2)(D).

[16] *See* NYSE Arca Equities Rule 8.600(d)(2)(C)(ii). With respect to trading halts, the Exchange may consider other relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Funds. Trading in Shares of the Funds will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

[17] *See* NYSE Arca Equities Rule 8.600(d)(2)(B)(ii).

[18] *See supra* note 5. The Commission notes that an investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (''Advisers Act''). As a result, the Adviser and Sub-Adviser and their related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[19] *See* 17 CFR 240.10A–3.

[20] 15 U.S.C. 78f(b)(5).

[21] 15 U.S.C. 78s(b)(2).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64692; File No. SR–NYSEArca–2011–37]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rules 5.30 and 5.32 To Permit the Exchange To List Flexible Exchange Options on Index and Equity Securities That Are Eligible for Non-FLEX Options Trading, and That Have Non-FLEX Options on Such Index and Equity Securities Listed and Traded on at Least One National Securities Exchange, Even if the Exchange Does Not List Such Non-FLEX Options

June 16, 2011.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on June 3, 2011, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Rules 5.30 and 5.32 to permit the Exchange to list Flexible Exchange Options (''FLEX Options'') on index and equity securities that are eligible for Non-FLEX Options trading, and that have Non-FLEX Options on such index and equity securities listed and traded on at least one national securities exchange, even if the Exchange does not list such Non-FLEX Options. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Rule 5.30 Applicability, Definitions, and References, and Rule 5.32, Terms of FLEX Options, to delete obsolete references and to permit trading of FLEX Options series in securities whose Non-FLEX Options are listed and traded on a national securities exchange(s), based on a recently adopted rule change of the Chicago Board Options Exchange (''CBOE'').[4]

Rules 5.30(a)(1) and 5.32(e)(1) currently permit FLEX Index Options on only four specific indexes, none of which are currently listed or traded on the Exchange. In addition, Rule 5.30(a)(2) currently permits FLEX Options on only one Exchange-Traded Fund Share (''ETF''). The Commission originally only approved trading of FLEX Options on a limited number of index products,[5] prior to approval of generic listing standards for index options, and the Exchange adopted rule text in a rule filing that restricted FLEX options to only one ETF, despite other general rule language in that rule filing that permitted FLEX options on any ETF.[6] In 2004, the Exchange had, in fact, deleted the references to specific indexes and to a specific ETF in the rules noted above,[7] but inadvertently reinstated the deleted text in a contemporaneous filing.[8] Subsequent listing of options on other index products did not include updating the relevant rule text in Rules 5.30 or 5.32.

The deletion of the restrictive language in Rules 5.30 and 5.32 will be accompanied by the adoption of new rule text, by which the Exchange is proposing to adopt a rule change similar to a rule change recently adopted by the CBOE to allow FLEX Equity Options [9] on any security that meets the standards of NYSE Arca Rule 5.3, and that has Non-FLEX Options on such security listed and traded on at least one options exchange, regardless of whether the Exchange trades such Non-FLEX Options.

Similarly, the CBOE rule change also adopted a provision to allow FLEX Index Options on any index that meets its listing standards. NYSE Arca proposes to adopt a similar provision that would permit FLEX Index Options on any index that meets the standards of Rule 5.12 or 5.13, and that has Non-FLEX Options on such index listed and traded on at least one options exchange, even if the Exchange does not list and trade such Non-FLEX Options.

As an alternative to the over-the-counter marketplace and other national security exchanges, the Exchange proposes in this rule filing to increase the spectrum of indexes and equity securities that are eligible for FLEX Options trading on the Exchange, even if the Exchange does not list Non-FLEX Options on such indexes or equity securities. In this regard, the Exchange does not list options on every NMS stock or index that is eligible for options trading, even if permitted to do so according to its listing standards, but recognizes that market participants may want access to options on such indexes and equity securities, subject to the certainty and safeguards that a regulated and standardized marketplace provides.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act [10] in general, and furthers the objectives of Section 6(b)(5) of the Act, in that it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes that its proposal to permit the Exchange to list FLEX Options on indexes and equity securities that are eligible for

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 60585 (August 28, 2009), 74 FR 46257 (September 8, 2009). Unlike CBOE's rule, we have clarified that our proposed rule would only permit the trading of FLEX Options on securities whose Non-Flex Options are listed and traded on at least one options exchange.

[5] *See* Securities Exchange Act Release No. 34364 (July 13, 1994), 59 FR 36813 (July 19, 1994).

[6] *See* Exchange Act Release No. 34–44025 (February 28, 2001), 66 FR 13986 (March 8, 2001). In particular, as part of this rule filing, the Exchange adopted the following rule text in Rule 8.102(f)(1), ''FLEX Equity Option transactions are limited to transactions in options on underlying securities or Exchange-Traded Fund Shares that have been approved by the Exchange in accordance with Rule 3.6.'' Rule 8.102 was subsequently renumbered as Rule 5.32.

[7] *See* Securities Exchange Act Release No. 49340 (February 27, 2004), 69 FR 10804 (March 8, 2004) (Notice of Filing and Immediate Effectiveness of PCX–2004–06).

[8] *See* Securities Exchange Act Release No. 49718 (May 17, 2004), 69 FR 29611 (May 24, 2004) (Order Approving PCX–2004–08).

[9] The Commission notes that options on ETFs, as discussed above, are considered FLEX Equity Options under NYSE Arca's rules. *See* NYSE Arca Rule 5.30(b)(5).

[10] 15 U.S.C. 78f(b).

Non-FLEX Options trading and whose Non-FLEX Options are listed and traded on at least one national securities exchange, even if the Exchange does not list such Non-FLEX Options, would provide market participants with additional means to manage their risk exposures and carry out their investment objectives with listed options. In this regard, the Exchange's proposal would increase competition in the FLEX Options market. In addition, the Exchange's proposal is consistent with investor protection and the public interest in that it is limited to FLEX Options on securities that would be eligible to have, and in fact have, Non-FLEX Options listed and traded on them. The criteria for such underlying securities has been carefully crafted over the years to ensure that only appropriate securities have standardized options listed on them (*e.g.,* securities with sufficient trading volume and shareholders).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(6) thereunder.[12]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [13] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [14] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the Exchange could immediately list FLEX Options on indexes and equity securities that are eligible for non-FLEX Options trading, and that have non-FLEX Options on such index and equity securities listed and traded on at least one national securities exchange, even if the Exchange does not list non-FLEX Options on such indexes and equity securities. In support of the waiver, the Exchange believes that its proposal is consistent with CBOE's rules, which were previously published for public comment, and would allow the Exchange to immediately compete with other exchanges for the trading of such FLEX Options.

The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest. In making this determination, the Commission notes that NYSE Arca's proposed rule change is substantially similar to CBOE's FLEX rules, which also permit CBOE to list FLEX options on securities that are eligible for non-FLEX options trading, even if CBOE does not list non-FLEX options on such securities.[15] The Commission notes that the CBOE's proposal was subject to full notice and comment, and the Commission received no comments on CBOE's rule proposal. Further, the Commission notes that NYSE Arca's proposal adds clarification to the rules, noting expressly that its rules would only permit the trading of FLEX Options on securities whose non-FLEX Options are listed and traded on at least one national securities exchange. This provision will help to ensure that adequate exchange requirements are met for trading these products and that the FLEX market will provide an alternative to certain investors that want to customize specified options terms not available in the standardized market. In addition to the factors noted above, the Commission also believes that waiver of the operative delay will allow the NYSE Arca to immediately compete with other exchanges for the trading of such FLEX options, thereby providing investors another venue on which to trade these products. For these reasons, the Commission designates, consistent with the protection of investors and the public interest, that the proposed rule change become operative immediately upon filing.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File No. SR–NYSEArca–2011–37 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NYSEArca–2011–37. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). Pursuant to Rule 19b–4(f)(6)(iii) under the Act, the Exchange is required to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission notes that the Exchange has satisfied this requirement.

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] *See supra* note 4.

[16] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NYSEArca–2011–37 and should be submitted on or before July 13, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–15606 Filed 6–21–11; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64688; File No. SR–Phlx–2011–56]

Self-Regulatory Organizations; The NASDAQ OMX PHLX LLC; Order Granting Approval of Proposed Rule Change Establishing a Qualified Contingent Cross Order for Execution on the Floor of the Exchange

June 16, 2011.

I. Introduction

On May 4, 2011, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish a qualified contingent cross order for execution on the floor of the Exchange (''Floor QCC Order''). The proposed rule change was published in the **Federal Register** on May 12, 2011.[3] The Commission received one comment letter on the proposal.[4] Phlx submitted a comment response letter on June 3, 2011.[5] This order grants approval of the proposed rule change.

II. Description of the Proposal

Phlx proposes to amend Rule 1064 to establish a Floor QCC Order type.[6]

As proposed, the Floor QCC Order would be required to: (i) Be for at least 1,000 contracts, (ii) meet the six requirements of Phlx Rule 1080(o)(3),[7] (iii) be executed at a price at or between the National Best Bid and Offer (''NBBO''); and (iv) be rejected if a Customer order is resting on the Exchange book at the same price. Specifically, proposed Phlx Rule 1064(e) would provide that Floor QCC Orders may be immediately executed upon entry into the system by an Options Floor Brokers and without exposure if no Customer Orders[8] exist on the Exchange's order book at the same price.

Floor QCC Orders would be electronically entered by an Options Floor Broker on the floor of the Exchange using the Floor Broker Management System (''FBMS'') and the orders would then be executed electronically. Only Options Floor Brokers would be permitted to enter Floor QCC Orders. In addition, under proposed Rule 1064(e)(2), Options Floor Brokers would be prohibited from entering Floor QCC Orders for their own accounts, the account of an associated person, or an account with respect to which it or an associated person thereof exercises investment discretion. The Exchange notes that the restrictions set forth in proposed Rule 1064(e)(2) do not limit in any way the obligation of Options Floor Brokers and other Exchange members to comply with Section 11(a) or the rules thereunder.[9]

Additionally, the Exchange proposes to modify subsections (a), (b), and (c) of Rule 1064 to establish that the requirements applicable to Floor QCC Orders that are set forth in new subsection (e) are distinct from those applicable to the orders described in such subsections.

III. Comment Letter

One commenter raised an objection to the proposal.[10] The commenter questioned the ability of a floor-based exchange to verify that there is not a customer order on the book at the price as a Floor QCC Order at the time of execution.[11] The commenter argued that in an electronic trading environment, an exchange's systems can automatically determine if there is a customer order on the book before a Floor QCC Order is executed.[12] The commenter stated that how this function would be performed on a floor-based exchange should be clarified, as well as what the time of execution would be for a floor-based trade.[13] The commenter argued that ''[a]llowing a QCC to be implemented in a non-automated environment without a systemic check of whether there is a customer order on the book at the time of execution would effectively eliminate the protections guaranteed in an all electronic trading environment, thus returning [the exchanges] to the unequal competitive environment from which the ISE's QCC proposal originated.''[14]

In its letter, Phlx responded to the issues raised in the ISE Letter and explained that, even when Floor QCC Orders are entered by the Options Floor Broker, they are submitted electronically to the Phlx order book where a systemic check would be performed to determine whether a customer order is resting on the book at

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[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 64415 (May 5, 2011), 76 FR 27732 (''Notice'').

[4] *See* Letter to Elizabeth M. Murphy, Secretary, Commission, from Michael J. Simon, Secretary, International Securities Exchange (''ISE''), dated May 27, 2011 (''ISE Letter'').

[5] *See* Letter to Elizabeth M. Murphy, Secretary, Commission, from Jeffrey S. Davis, Vice President and Deputy General Counsel, Phlx, dated June 3, 2011 (''Phlx Response Letter'').

[6] Phlx established an electronic QCC Order set forth in PHLX Rule 1080(o). *See* Securities Exchange Act Release No. 64249 (April 7, 2011), 76 FR 20773 (April 13, 2011) (SR–Phlx–2011–047).

[7] Phlx Rule 1080(o)(3) defines a qualified contingent cross trade substantively identical to the Commission's definition in the QCT Release. A qualified contingent cross trade must meet the following conditions: (i) At least one component must be an NMS stock, as defined in Rule 600 of Regulation NMS, 17 CFR 242.600; (ii) all components must be effected with a product or price contingency that either has been agreed to by all the respective counterparties or arranged for by a broker-dealer as principal or agent; (iii) the execution of one component must be contingent upon the execution of all other components at or near the same time; (iv) the specific relationship between the component orders (*e.g.,* the spread between the prices of the component orders) is determined by the time the contingent order is placed; (v) the component orders must bear a derivative relationship to one another, represent different classes of shares of the same issuer, or involve the securities of participants in mergers or with intentions to merge that have been announced or cancelled; and (vi) the transaction must be fully hedged (without regard to any prior existing position) as a result of other components of the contingent trade. The Commission has granted an exemption for QCTs that meet certain requirements from Rule 611(a) of Regulation NMS, 17 CFR 242.611(a) (''QCT Exemption''). *See* Securities Exchange Act Release No. 57620 (April 4, 2008), 73 FR 19271 (April 9, 2008) (''QCT Release,'' which supersedes a release initially granting the QCT exemption, Securities Exchange Act Release No. 54389 (August 31, 2006), 71 FR 52829 (September 7, 2006) (''Original QCT Release'')).

[8] Phlx would reject Floor QCC Orders that attempt to execute when any Customer Orders are resting on the Exchange limit order book at the same price.

[9] Proposed Rule 1064(e)(2) would also require Options Floor Brokers to maintain books and records demonstrating that no Floor QCC Order was entered by an Options Floor Broker in such a prohibited account.

[10] *See* note 4, *supra.*

[11] *See* ISE Letter.

[12] *Id.*

[13] *Id.*

[14] *Id.*

the same price as any leg of the Floor QCC Order, in which case the Phlx trading system would reject the entire Floor QCC Order.[15] If, however, there is no customer order resting on the Phlx book at the same price as any leg of the Floor QCC order, the system would execute the Floor QCC Order and simultaneously assign it an execution time.[16]

IV. Discussion and Commission's Findings

The Commission has carefully reviewed the proposed rule change, the one comment letter received, and finds that it is consistent with the requirements of Section 6(b) of the Act.[17] Specifically, the Commission finds that the proposal is consistent with Sections 6(b)(5)[18] and 6(b)(8),[19] which require, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and that the rules of an exchange do no impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In addition, the Commission finds that the proposed rule change is consistent with Section 11A(a)(1)(C) of the Act,[20] in which Congress found that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure, among other things, the economically efficient execution of securities transactions.

The Commission believes that the proposed rule change, which would permit a clean cross of the options leg of a subset of qualified contingent trades from the Exchange floor, is appropriate and consistent with the Act.[21] The Commission believes that the Floor QCC Order type may facilitate the execution of qualified contingent trades, which the Commission found to be beneficial to the market as a whole by contributing to the efficient functioning of the securities markets and the price discovery process.[22] The Floor QCC Order would provide assurance to parties to stock-option qualified contingent trades that their hedge would be maintained by allowing the options component to be executed as a clean cross.

While the Commission believes that order exposure is generally beneficial to options markets in that it provides an incentive to options market maker to provide liquidity and therefore plays an important role in ensuring competition and price discovery in the options markets, it also has recognized that contingent trades can be ''useful trading tools for investors and other market participants, particularly those who trade the securities of issuers involved in mergers, different classes of shares of the same issuers, convertible securities, and *equity derivatives such as options* [italics added],''[23] and that ''[t]hose who engage in contingent trades can benefit the market as a whole by studying the relationships between prices of such securities and executing contingent trades when they believe such relationships are out of line with what they believe to be fair value.''[24] As such, the Commission stated that the transactions that meet the specified requirements of the QCT Exemption could be of benefit to the market as a whole, contributing to the efficient functioning of the securities markets and the price discovery process.[25]

Thus, in light of the benefits provided by both the requirement for exposure as well as by qualified contingent trades such as Floor QCC Orders, the Commission must weigh the relative merits of both for the options markets.[26] The Commission believes that the proposal, in requiring a Floor QCC Order be: (1) Part of a qualified contingent trade under Regulation NMS; (2) for at least 1,000 contracts; (3) executed at a price at or between the NBBO; and (4) rejected if there is a public customer on the electronic book, strikes an appropriate balance for the options market in that it is narrowly drawn and establishes a limited exception to the general principle of exposure and retains the general principle of customer priority in the options markets. Furthermore, not only must a Floor QCC Order be part of a qualified contingent trade by satisfying each of the six underlying requirements of the QCT Exemption, the requirement that a QCC Order be for a minimum size of 1,000 contracts provides another limit to its use by ensuring only transactions of significant size may avail themselves of this order type.[27]

The Commission notes that, under Phlx's proposal, Floor QCC Orders must be submitted by an Options Floor Broker electronically from on the floor through Phlx's FBMS. Phlx has represented that to effect Floor QCC Orders, members must ensure that their orders comply with Section 11(a)(1) of the Act,[28] which concerns proprietary trading on an exchange by an exchange member, and the rules thereunder.

Additionally, the Commission believes that the Phlx Response Letter clarified the questions raised by ISE in the ISE Letter.

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5)[29] and 6(b)(8)[30] of the Act. Further, the Commission finds that the proposed rule change is consistent with Section 11A(a)(1)(C) of the Act.[31]

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[32] that the proposed rule change (SR–Phlx–2011–56) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Cathy H. Ahn,

Deputy Secretary.

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[15] *See* Phlx Response Letter, *supra* note 5.

[16] *Id.*

[17] 15 U.S.C. 78f(b). In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 15 U.S.C. 78f(b)(5).

[19] 15 U.S.C. 78f(b)(8).

[20] 15 U.S.C. 78k–1(a)(1)(C).

[21] *See also* Securities Exchange Act Release No. 63955 (February 24, 2011), 76 FR 11533 (March 2, 2011) (SR–ISE–2010–73).

[22] *See* Original QCT Release, *supra* note 7.

[23] *See id.* at 52830–52831.

[24] *Id.*

[25] *See* QCT Release, *supra* note 7 at 19273.

[26] The Commission notes that it has previously permitted the crossing of two public customer orders, for which no exposure is required on ISE and CBOE. *See* CBOE Rule 6.74A.09 and ISE Rule 715(i) and 721.

[27] The Commission notes that the requirement that clean crosses be of a certain minimum size is not unique to the Floor QCC Order. *See, e.g.,* NSX 11.12(d), which requires, among other things, that a Clean Cross be for at least 5,000 shares and have an aggregate value of at least $100,000.

[28] 15 U.S.C. 78k(a)(1). Generally, Section 11(a)(1) of the Act restricts any member of a national securities exchange from effecting any transaction on such exchange for: (i) the member's own account, (ii) the account of a person associated with the member, or (iii) an account over which the member or a person associated with the member exercises discretion, unless a specific exemption is available.

[29] 15 U.S.C. 78f(b)(5).

[30] 15 U.S.C. 78f(b)(8).

[31] 15 U.S.C. 78k–1(a)(1)(C).

[32] 15 U.S.C. 78s(b)(2).

[33] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64689; File No. SR–NYSEArca–2011–18]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Granting Approval of Proposed Rule Change To List and Trade the Meidell Tactical Advantage ETF

June 16, 2011.

I. Introduction

On April 15, 2011, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of the Meidell Tactical Advantage ETF (''Fund'') under NYSE Arca Equities Rule 8.600. The proposed rule change was published in the **Federal Register** on May 3, 2011.[3] The Commission received no comments on the proposal. This order grants approval of the proposed rule change.

II. Description of the Proposal

The Exchange proposes to list and trade the Shares of the Fund pursuant to NYSE Arca Equities Rule 8.600. The Shares will be offered by AdvisorShares Trust (''Trust''), a statutory trust organized under the laws of the State of Delaware and registered with the Commission as an open-end management investment company.[4] The investment adviser to the Fund is AdvisorShares Investments, LLC (''Adviser''). American Wealth Management is the Fund's sub-adviser (''Sub-Adviser'') and provides day-to-day portfolio management of the Fund. Foreside Fund Services, LLC (''Distributor'') is the principal underwriter and distributor of the Fund's Shares. The Exchange states that neither the Adviser nor the Sub-Adviser is affiliated with a broker-dealer.[5]

Description of the Fund

The Fund's investment objective is to seek to provide long-term capital appreciation with a secondary emphasis on capital preservation. The Fund is an actively managed exchange-traded fund (''ETF'') and, thus, does not seek to replicate the performance of a specified index. The Fund is considered a ''fund-of-funds'' that seeks to achieve its investment objective by primarily investing in other ETFs that offer diversified exposure to global regions, countries, styles (market capitalization, value, growth, etc.) or sectors, and other exchange-traded products (''ETPs,'' and, together with ETFs, ''Underlying ETPs''),[6] including, but not limited to, exchange-traded notes (''ETNs''), exchange-traded currency trusts, and closed-end funds. The Fund will primarily invest in U.S.-listed domestic and foreign equity-based, fixed income-based, currency-based, and commodity-based Underlying ETPs.

The Sub-Adviser will seek to achieve the Fund's investment objective by managing a tactical strategy that has the ability to dynamically rebalance the Fund's portfolio from as much as 100% equity-based assets to 100% fixed income-based assets or cash and cash equivalents depending on market trends. This is a long-only tactical strategy that seeks to minimize portfolio losses by rotating out of higher volatility assets and into lower volatility assets when the Sub-Adviser believes there are significant risks in the equity markets. Risk management is an integral part of the Sub-Adviser's investment strategy. The Sub-Adviser will use a quantitative tactical methodology to identify the Underlying ETPs believed to be participating in long-term ''durable trends'' within the market. This model will enable the Sub-Adviser to evaluate, rank, and select the appropriate mix of investments in Underlying ETPs given market conditions.

The Sub-Adviser's investment philosophy emphasizes investments in broad market indexes and market sector indexes. In general, the Fund will purchase or increase its exposure to Underlying ETPs that track equity markets or market sectors when the Sub-Adviser's quantitative tactical asset allocation model and risk analysis indicate that the applicable market or sector is at low risk of losing value or presents opportunity for growth and appreciation. The Fund will generally sell interests in, or reduce investment exposure to, Underlying ETPs tracking equity markets or market sectors in favor of fixed income-based Underlying ETPs or cash positions when the Sub-Adviser's quantitative tactical asset allocation model and risk analysis indicate that such markets have become, or are becoming, risky.

The Sub-Adviser will use a quantitative metric to rank and select the appropriate mix of investments given prevailing market conditions. The Sub-Adviser's quantitative tactical asset allocation model determines asset allocation between bonds and stocks, equity selection, sector concentration, as well as limiting portfolio drawdown. The general guidelines for the Fund's portfolio are as follows:

Assets Held by Underlying ETPs	
Equity-Based	0%–100%
Fixed Income-Based/Cash	0%–100%

Depending on the economic and market climate, the portfolio may increase or decrease portfolio concentrations within the ranges shown below.

Foreign Equity	0%–50%
Large Cap Equity	0%–50%
Mid Cap Equity	0%–30%
Small Cap Equity	0%–30%
Commodities	0%–20%
Currencies	0%–10%

The Fund's portfolio may temporarily exceed these percentage ranges for short periods without notice, and the Sub-Adviser may alter the percentage ranges when it deems appropriate.

Additional quantitative tools will be used to evaluate the probability of investment success within the equity market. These tools will allow the Sub-Adviser to get into or out of equity positions and will include, but are not limited to: (1) Interest rate spreads; (2) options activity; (3) market breadth; and (4) equity index trends.

The Fund intends to invest primarily in the securities of Underlying ETPs consistent with the requirements of Section 12(d)(1) of the 1940 Act, or any rule, regulation, or order of the Commission or interpretation thereof. In addition, the Fund will only make such

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 64357 (April 28, 2011), 76 FR 24936 (''Notice'').

[4] The Trust is registered under the Investment Company Act of 1940 (''1940 Act''). On March 15, 2011, the Trust filed with the Commission Post-Effective Amendment No. 20 to Form N–1A under the Securities Act of 1933 (15 U.S.C. 77a) and under the 1940 Act relating to the Fund (File Nos. 333–157876 and 811–22110) (''Registration Statement'').

[5] *See* Commentary .06 to NYSE Arca Equities Rule 8.600. The Exchange represents that, in the event (a) the Adviser or Sub-Adviser becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser becomes affiliated with a broker-dealer, such adviser and/or sub-adviser will implement a fire wall with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

[6] Underlying ETPs include Investment Company Units (as described in NYSE Arca Equities Rule 5.2(j)(3)); Index-Linked Securities (as described in NYSE Arca Equities Rule 5.2(j)(6)); Portfolio Depositary Receipts (as described in NYSE Arca Equities Rule 8.100); Trust Issued Receipts (as described in NYSE Arca Equities Rule 8.200); Commodity-Based Trust Shares (as described in NYSE Arca Equities Rule 8.201); Currency Trust Shares (as described in NYSE Arca Equities Rule 8.202); Commodity Index Trust Shares (as described in NYSE Arca Equities Rule 8.203); Trust Units (as described in NYSE Arca Equities Rule 8.500); Managed Fund Shares (as described in NYSE Arca Equities Rule 8.600); and closed-end funds.

investments in conformity with the requirements of Section 817 of the Internal Revenue Code of 1986, as amended (''Code'').

Other Investments of the Fund

The Fund may invest 100% of its total assets in high-quality debt securities and money market instruments either directly or through Underlying ETPs to respond to adverse market, economic, political, or other conditions.[7] The Fund may be invested in these instruments for extended periods, depending on the Sub-Adviser's assessment of market conditions. These debt securities and money market instruments include shares of other mutual funds, commercial paper, certificates of deposit, bankers' acceptances, U.S. Government securities, repurchase and reverse repurchase agreements, and bonds that are BBB or higher.

The Fund will not (i) with respect to 75% of its total assets, purchase securities of any issuer (except securities issued or guaranteed by the U.S. Government, its agencies or instrumentalities, or shares of investment companies) if, as a result, more than 5% of its total assets would be invested in the securities of such issuer, or (ii) acquire more than 10% of the outstanding voting securities of any one issuer. For purposes of this policy, the issuer of the underlying security will be deemed to be the issuer of any respective American Depositary Receipts (''ADRs'') or Global Depositary Receipts (''GDRs'').[8]

The Fund may not invest 25% or more of its total assets in the securities of one or more issuers conducting their principal business activities in the same industry or group of industries. This limitation does not apply to investments in securities issued or guaranteed by the U.S. Government, its agencies or instrumentalities, or shares of investment companies. The Fund will not invest 25% or more of its total assets in any investment company that so concentrates. For purposes of this policy, the issuer of the underlying security will be deemed to be the issuer of any respective ADRs or GDRs.

The Fund will seek to qualify for treatment as a Regulated Investment Company under the Code. In addition, the Fund will not: (1) Purchase illiquid securities; (2) except for Underlying ETPs that may hold non-U.S. issues, invest in non-U.S. issues; and (3) invest in leveraged, inverse, or inverse leveraged Underlying ETPs. Additional information regarding the Trust, the Fund, and the Shares, the Fund's investment strategies, risks, creation and redemption procedures, fees, portfolio holdings and disclosure policies, distributions and taxes, availability of information, trading rules and halts, and surveillance procedures, among other things, can be found in the Notice and the Registration Statement, as applicable.[9]

III. Discussion and Commission's Findings

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of Section 6 of the Act[10] and the rules and regulations thereunder applicable to a national securities exchange.[11] In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[12] which requires, among other things, that the Exchange's rules be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission notes that the Shares must comply with the requirements of NYSE Arca Equities Rule 8.600 to be listed and traded on the Exchange.

The Commission finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Act,[13] which sets forth Congress's finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities. Quotation and last-sale information for the Shares will be available via the Consolidated Tape Association high-speed line and, for the Underlying ETPs, will be available from the national securities exchange(s) on which they are listed. In addition, the Portfolio Indicative Value (''PIV''), as defined in NYSE Arca Equities Rule 8.600(c)(3), will be disseminated by one or more major market data vendors at least every 15 seconds during the Core Trading Session. On each business day, before commencement of trading in Shares during the Core Trading Session on the Exchange, the Fund will disclose on its Web site the Disclosed Portfolio, as defined in NYSE Arca Equities Rule 8.600(c)(2), that will form the basis for the Fund's calculation of the net asset value (''NAV'') at the end of the business day.[14] The NAV of the Fund will normally be determined as of the close of the regular trading session on the New York Stock Exchange (''NYSE'') (ordinarily 4 p.m. Eastern Time) on each business day. A basket composition file, which includes the security names and share quantities required to be delivered in exchange for Fund shares, together with estimates and actual cash components, will be publicly disseminated daily prior to the opening of the NYSE via the National Securities Clearing Corporation. Information regarding market price and trading volume of the Shares is and will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. The Fund's Web site will also include a form of the prospectus for the Fund, information relating to NAV (updated daily), and

[7] Adverse market conditions would include large downturns in the broad market value of two or more times current average volatility, where the Sub-Adviser views such downturns as likely to continue for an extended period of time. Adverse economic conditions would include significant negative results in factors deemed critical at the time by the Sub-Adviser, including significant negative results regarding unemployment, Gross Domestic Product, consumer spending or housing numbers. Adverse political conditions would include events such as government overthrows or instability, where the Sub-Adviser expects that such events may potentially create a negative market or economic condition for an extended period of time. E-mail from Timothy J. Malinowski, Senior Director, NYSE Euronext, to Edward Y. Cho, Special Counsel, Division of Trading and Markets, Commission, dated June 8, 2011.

[8] ADRs, as well as GDRs, are certificates evidencing ownership of shares of a foreign issuer, and may be sponsored or unsponsored. These certificates are issued by depositary banks and generally trade on an established market in the United States or elsewhere. The underlying shares are held in trust by a custodian bank or similar financial institution in the issuer's home country. The depositary bank may not have physical custody of the underlying securities at all times and may charge fees for various services, including forwarding dividends and interest and corporate actions.

[9] *See* Notice and Registration Statement, *supra* notes 3 and 4, respectively.

[10] 15 U.S.C. 78f.

[11] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[12] 17 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[14] On a daily basis, the Adviser will disclose for each portfolio security or other financial instrument of the Fund the following information: Ticker symbol (if applicable); name of security or financial instrument; number of shares or dollar value of financial instruments held in the portfolio; and percentage weighting of the security or financial instrument in the portfolio.

other quantitative and trading information.

The Commission further believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Commission notes that the Exchange will obtain a representation from the issuer of the Shares that the NAV will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.[15] In addition, the Exchange will halt trading in the Shares under the specific circumstances set forth in NYSE Arca Equities Rule 8.600(d)(2)(D) and may halt trading in the Shares if trading is not occurring in the securities and/or the financial instruments comprising the Disclosed Portfolio of the Fund, or if other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.[16] Further, the Commission notes that the Reporting Authority that provides the Disclosed Portfolio must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the actual components of the portfolio.[17] The Exchange states that it has a general policy prohibiting the distribution of material, non-public information by its employees, and neither the Adviser nor the Sub-Adviser is affiliated with a broker-dealer.[18]

The Exchange represents that the Shares are deemed to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. In support of this proposal, the Exchange has made representations, including:

(1) The Shares will conform to the initial and continued listing criteria under NYSE Arca Equities Rule 8.600.

(2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(3) The Exchange's surveillance procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable Federal securities laws.

(4) Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (a) The procedures for purchases and redemptions of Shares in Creation Unit aggregations (and that Shares are not individually redeemable); (b) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its Equity Trading Permit Holders to learn the essential facts relating to every customer prior to trading the Shares; (c) the risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated PIV will not be calculated or publicly disseminated; (d) how information regarding the PIV is disseminated; (e) the requirement that Equity Trading Permit Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading and other information.

(5) For initial and/or continued listing, the Fund will be in compliance with Rule 10A–3 under the Act,[19] as provided by NYSE Arca Equities Rule 5.3.

(6) The Fund will not: (a) Purchase illiquid securities; (b) invest in non-U.S. issues (except for Underlying ETPs that may hold non-U.S. issues); and (c) invest in leveraged, inverse, or inverse leveraged Underlying ETPs.

(7) A minimum of 100,000 Shares of the Fund will be outstanding at the commencement of trading on the Exchange.

This approval order is based on the Exchange's representations.

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act[20] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[21] that the proposed rule change (SR–NYSEArca–2011–18) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Cathy H. Ahn,

Deputy Secretary.

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[15] *See* NYSE Arca Equities Rule 8.600(d)(1)(B).

[16] *See* NYSE Arca Equities Rule 8.600(d)(2)(C)(ii). With respect to trading halts, the Exchange may consider other relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund. Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

[17] *See* NYSE Arca Equities Rule 8.600(d)(2)(B)(ii).

[18] *See supra* note 5 and accompanying text. The Commission notes that an investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (''Advisers Act''). As a result, the Adviser and Sub-Adviser and their related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[19] *See* 17 CFR 240.10A–3.

[20] 15 U.S.C. 78f(b)(5).

[21] 15 U.S.C. 78s(b)(2).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64691; File No. SR–NASDAQ–2011–079]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Implementation Date for Several Rules in Connection With Trading System Enhancements

June 16, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4[2] thereunder, notice is hereby given that on June 8, 2011, The NASDAQ Stock Market LLC (''Exchange'' or ''NASDAQ'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASDAQ is filing with the Securities and Exchange Commission (''Commission'') a proposal for the NASDAQ Options Market (''NOM'') to extend the time period where certain rules, in connection with several trading system enhancements, are implemented from May 2011 to August 2011, as described below. The Exchange will announce the specific implementation schedule by Options Trader Alert, once the rollout schedule is finalized.

The text of the proposed rule change is available at *http://nasdaq.cchwallstreet.com/,* at NASDAQ's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to extend the time period where certain rules, in connection with several trading system enhancements, are implemented from May 2011 to August 2011. The Exchange intends to rollout these enhancements in August 2011.[3] The Exchange will announce the specific implementation schedule by Options Trader Alert, once the rollout schedule is finalized.

Previously, the Exchange filed two proposed rule changes indicating an implementation date of May 31, 2011.[4] The first one amended various rules to: (a) Permit market maker assignment by option rather than by series; (b) adopt a $5 quotation spread parameter; and (c) amend the quoting requirement for Market Makers.[5] The second one modified the procedures for the opening of trading at the start of the trading day and at the resumption of trading following a trading halt on NOM.[6] The implementation of both of those rules is now scheduled for August 2011. At the time the Exchange filed those two filings, the Exchange expected implementation to occur in May. However, since that time, additional enhancements have been finalized and filed as well,[7] all of which are intended to be implemented together. The Exchange needed more time to implement the enhancements. As a result, participants will have additional time to adapt to the enhancements.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[8] in general, and furthers the objectives of Section 6(b)(5) of the Act[9] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market and a national market system, and, in general, to protect investors and the public interest, because it merely extends an implementation period for two NOM enhancements, which should provide NOM Participants additional time to adapt to the enhancements.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11]

The Exchange has requested the Commission to waive the 30-day operative delay so that NOM Participants will know that these two rules are not yet implemented. The Exchange noted that it will announce the specific implementation schedule by Options Trader Alert, once the rollout schedule is finalized. The Commission hereby grants the Exchange's request and believes such waiver is reasonable as it would provide notice to NOM participants with respect to the change in implementation date and is consistent with the protection of investors and the public interest.[12] Accordingly, the Commission designates the proposed rule change operative upon filing with the Commission.

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.

[3] The Commission notes that NASDAQ intends to begin implementation of these two rules by August 31, with the specific implementation scheduled to be announced via Options Trader Alert, as stated above. In the event that this does not occur by August 31, NASDAQ has represented that it will file a proposed rule change to establish the revised time period. *See* e-mail from Edith Callahan, Principal Associate General Counsel, The NASDAQ OMX Group, Inc., to Steve L. Kuan, Special Counsel, Division of Trading and Markets, Commission, on June 16, 2011.

[4] The Exchange has also filed other proposed rule changes in connection with these enhancements, but established the implementation date as on or about August 1, 2011, such that it does not need to be revised.

[5] Securities Exchange Act Release No. 64054 (March 8, 2011), 76 FR 14111 (March 15, 2011) (SR–NASDAQ–2011–036). The implementation date in the filing was May 31, 2011.

[6] Securities Exchange Act Release No. 64463 (May 11, 2011), 76 FR 28257 (May 16, 2011) (SR–NASDAQ–2011–037). The implementation date in the filing was May 31, 2011.

[7] *See e.g.,* Securities Exchange Act Release No. 64312 (April 20, 2011), 76 FR 23351 (April 26, 2011) (SR–NASDAQ–2011–053).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the self-regulatory organization to submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] For purposes only of waiving the 30-day operative delay of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2011–079 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2011–079. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing 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–2011–079 and should be submitted on or before July 13, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–15555 Filed 6–21–11; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice 7508]

Determination Pursuant to the Foreign Missions Act

Pursuant to the authority vested in me under the Foreign Missions Act (FMA), 22 U.S.C. 4301 *et seq.,* and specifically 22 U.S.C. 4304(b) and (c), and by the authority vested in me under the FMA and Delegation of Authority No. 147 of September 13, 1982, and Delegation of Authority No. 198 of September 16, 1992, I hereby determine that it is reasonably necessary on the basis of reciprocity or otherwise to adjust for costs and procedures of obtaining benefits for missions of the United States abroad that the benefit of obtaining zoning approval and permit issuances associated with the construction of the People's Republic of China's diplomatic and consular facilities and residences in the United States, be predicated on the payment of surcharges, calculated by the Department's Office of Foreign Missions (OFM) to reflect the fee the U.S. Embassy in Beijing and its consular posts are required to pay the Beijing Service Bureau for Diplomatic Missions, or its regional counterparts, for the provision of services associated with the filing and approval matters pertaining to the construction of diplomatic or consular facilities in China. The authority to regulate foreign mission benefits under the FMA has been delegated to the Director of the Office of Foreign Missions (Delegation of Authority No. 214).

Dated: June 14, 2011.

Patrick J. Kennedy,

Under Secretary for Management.

[FR Doc. 2011–15626 Filed 6–21–11; 8:45 am]

BILLING CODE 4710–43–P

DEPARTMENT OF STATE

[Public Notice 7474]

U.S. Advisory Commission on Public Diplomacy; Notice of Meeting

The U.S. Advisory Commission on Public Diplomacy will hold a public meeting from 10 a.m. to 12 p.m. on July 12, 2011, at the Capitol Visitor's Center, room SVC 203–02.

The meeting will include discussions on funding public diplomacy and the Smith-Mundt Act. The Commission welcomes commentary from subject matter experts from several organizations, including the State Department, the Broadcasting Board of Governors, the Congress, and the public on this and other relevant topics.

This meeting is open to the public, Members and staff of Congress, the State Department, Defense Department, the media, and other governmental and non-governmental organizations. To attend or request further information, contact the Commission at (202) 203–7463 or *pdcommission@state.gov* by 3 p.m. on July 11, 2011. Please arrive for the meeting at least 15 minutes early to allow for a prompt meeting start.

The U.S. Advisory Commission on Public Diplomacy is charged with appraising U.S. Government activities intended to understand, inform, and influence foreign publics. The Commission formulates and recommends to the President, the Secretary of State, and Members of Congress, policies and programs to carry out the public diplomacy functions vested in the State Department, Broadcasting Board of Governors and other government entities. The Commission may submit reports to the Congress, the President, and the Secretary of State on public diplomacy programs and activities. The Commission makes reports available to the public in the United States and abroad to develop a better understanding of and support for public diplomacy programs. These reports are subject to the approval of the Chairperson, in consultation with the Executive Director.

The Commission consists of seven members appointed by the President, by and with the advice and consent of the Senate. The members of the Commission shall represent the public interest and shall be selected from a cross section of educational, communications, cultural, scientific, technical, public service, labor, business, and professional backgrounds. Not more than four members shall be from any one political party. The President designates a member to chair the Commission.

The current members of the Commission are: Mr. William Hybl of Colorado, Chairman; Ambassador Lyndon Olson of Texas, Vice Chairman; Mr. Jay Snyder of New York; Ambassador Penne Korth-Peacock of Texas; Ms. Lezlee Westine of Virginia;

[13] 17 CFR 200.30–3(a)(12).

and, Mr. Sim Farar of California. The seventh seat on the Commission is currently vacant.

The following individual has been nominated to the Commission but awaits Senate confirmation as of this writing: Anne Wedner of Illinois. Ms. Wedner will replace Mr. Jay Snyder on the Commission.

The Commission was established under Section 604 of the United States Information and Educational Exchange Act of 1948, commonly known as the Smith-Mundt Act, as amended (22 U.S.C. 1469) and Section 8 of Reorganization Plan Numbered 2 of 1977. The U.S. Advisory Commission on Public Diplomacy is authorized by Public Law 101–246 (2009), 22 U.S.C. 6553, and has been further authorized through September 20, 2011.

Dated: June 15, 2011.

Matthew C. Armstrong,

Executive Director, Department of State.

[FR Doc. 2011–15628 Filed 6–21–11; 8:45 am]

BILLING CODE 4710–11–P

DEPARTMENT OF STATE

[Public Notice 7473]

Shipping Coordinating Committee; Notice of Committee Meeting

The Shipping Coordinating Committee (SHC) will conduct an open meeting at 1 p.m. on Thursday, July 21, 2011, in Room 5–1224 of the United States Coast Guard Headquarters Building, 2100 Second Street, SW., Washington, DC 20593–0001. The primary purpose of the meeting is to prepare for the fifty fourth Session of the International Maritime Organization's (IMO) Subcommittee on Stability and Load Lines and on Fishing Vessels Safety (SLF) to be held at the IMO Headquarters, United Kingdom, January 16–20, 2012.

The primary matters to be considered include:

—Adoption of the agenda.
—Decisions of other IMO bodies.
—Development of second generation intact stability criteria
—Development of performance standards on time-dependent survivability of passenger ships in damaged condition.
— Development of guidelines for verification of damage stability requirements for tankers.
—Revision of the damage stability regulations for ro-ro passenger ships.
—Development of amendments to SOLAS chapter II–1 subdivision standards for cargo ships.
—Revision of SOLAS chapter II–1 subdivision and damage stability regulations.
—Development of provisions to ensure the integrity and uniform implementation of the 1969 TM Convention.
—Development of amendments to part B of the 2008 IS Code on towing and anchor operations.
—Consideration of IACS unified interpretations.
—Development of amendments to the criterion for maximum angle of heel in turns of the 2008 IS Code.
—Development of amendments to SOLAS regulation II–1/4 concerning subdivision standards for cargo ships.
—Biennial agenda and provisional agenda for SLF 55.
—Election of Chairman and Vice-Chairman for 2013.
—Any other business.
—Report to the Maritime Safety Committee.
—Consideration of the report of the Committee on its fifty fourth session.

Members of the public may attend this meeting up to the seating capacity of the room. To facilitate the building security process, and to request reasonable accommodation, those who plan to attend should contact the meeting coordinator, LCDR Catherine Phillips, by e-mail at *Catherine.A.Phillips@uscg.mil,* by phone at (202) 372–1374, by fax at (202) 372–1925, or in writing at Commandant (CG–5212), U.S. Coast Guard, 2100 2nd Street, SW., Stop 7126, Washington, DC 20593–7126 not later than July 14, 2011, 7 days prior to the meeting. Requests made after July 14, 2011 might not be able to be accommodated. Please note that due to security considerations, two valid, government issued photo identifications must be presented to gain entrance to the Headquarters building. The Headquarters building is accessible by taxi and privately owned conveyance (public transportation is not generally available). However, parking in the vicinity of the building is extremely limited. Additional information regarding this and other IMO SHC public meetings may be found at: *http://www.uscg.mil/imo.*

Dated: June 14, 2011.

Greg O'Brien,

Shipping Coordinating Committee, Department of State.

[FR Doc. 2011–15627 Filed 6–21–11; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement; Nueces County, TX

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Intent (NOI).

SUMMARY: Pursuant to 40 CFR 1508.22 and 43 TAC § 2.5(e)(2), the FHWA and the Texas Department of Transportation (TxDOT) are issuing this notice to advise the public that an environmental impact statement (EIS) will be prepared for the proposed United States (US) Highway 181 Harbor Bridge replacement/State Highway (SH) 286 (Crosstown Expressway) improvement project in Nueces County, Texas. The project and study limits include the US 181 and Beach Avenue interchange on the north and the SH 286 and Morgan Avenue interchange on the south. Areas within the city of Corpus Christi are included in the study area. The project will be developed in compliance with Section 6002 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) and the National Environmental Policy Act (NEPA).

FOR FURTHER INFORMATION CONTACT: Gregory Punske, P.E., District Engineer, Federal Highway Administration—Texas Division, 300 East 8th Street, Austin, Texas 78701. *Telephone:* 512–536–5960.

SUPPLEMENTARY INFORMATION: The US 181 Harbor Bridge project is listed in the Corpus Christi Metropolitan Planning Organization's Metropolitan Transportation Plan 2010–2035 (the long range transportation plan) as construction of a new bridge over the Corpus Christi Ship Channel. An NOI for this project was first published on May 20, 2005, for proposed improvements that included replacement of the existing Harbor Bridge and approaches where US 181 crosses the Corpus Christi Ship Channel, a roadway distance of approximately 2.25 miles. On March 20, 2007, a revised NOI was published to advise the public that the study limits described in the 2005 NOI had been expanded to accommodate added capacity that might have included managed lanes or various tolling strategies; the primary change was to the southern limit which would have extended the project along SH 286 to SH 358 (South Padre Island Drive). On November 3, 2010, the revised NOI published in 2007 was rescinded, via a notice in the **Federal Register**, because

of changes in the scope (managed toll lanes) and limits. The project limits have now been revised to eliminate the added capacity that would have included managed lanes and various tolling strategies and have been reduced on the south end back to SH 286 and Morgan Avenue. The new project limits are as follows: the northern limit is the US 181 and Beach Avenue interchange located north of the Corpus Christi Ship Channel but south of the Nueces Bay Causeway; the southern limit is SH 286 between Morgan Avenue and Baldwin Boulevard; the eastern limit is the Interstate Highway (I)–37/U.S. 181 intersection with Shoreline Boulevard in the Corpus Christi central business district (CBD); and the western limit is the I–37 and Nueces Bay Boulevard interchange. The new project limits total approximately 4.5 miles in length from north to south along US 181 and SH 286 and approximately 2.1 miles in length from east to west along I–37.

The proposed US 181 Harbor Bridge replacement is based on several needs: safety concerns, lack of capacity (need for additional travel lanes), connectivity to local roadways, poor level of service, and increasing traffic demand. In addition to these needs, the bridge's existing structure also has deficiencies, including high maintenance costs and navigational restrictions. The proposed improvements both to US 181/SH 286 and Harbor Bridge will address the structural deficiencies and navigational restrictions and improve safety, connectivity, and level of service in the study area.

The purpose of the project is to correct these established needs identified above and to promote, enhance and spur economic development in the area. It is anticipated that additional larger ship traffic is expected at the Port of Corpus Christi. The impacts and benefits of such will also be analyzed in the indirect and cumulative impacts analyses for the subject project.

Alternatives under consideration include (1) taking no action, and (2) Transportation System Management (TSM)/Transportation Demand Management, and (3) replacing the existing US 181 Harbor Bridge and approach roads with a facility that meets current highway design standards. A Feasibility Study completed in 2003 evaluated four build corridor alternatives, one along the existing alignment and three along new location alignments, as well as the No-build alternative. The Feasibility Study resulted in the identification of a recommended study corridor (new location alignment) for the bridge replacement component. All reasonable alternatives, that meet Purpose and Need of the project, including the alternatives developed in the Feasibility Study, will be identified and evaluated in the EIS, in addition to the No-build Alternative, based on input from Federal, state, and local agencies, as well as private organizations and concerned citizens.

Impacts caused by the construction and operation of the proposed improvements would vary depending on the alternative alignment used. At this time, to the best of our knowledge, significant impacts are anticipated in and to the community; including but not limited to: impacts to residences and businesses, including displacement; impacts to public parkland; social and economic impacts, including impacts to minority and low-income communities; and impacts to historic properties including the bridge itself. Additional impacts could potentially include the following: transportation impacts (construction detours, construction traffic, and mobility improvement); air quality and noise impacts from construction equipment and operation of the roadway; impacts to threatened and endangered species; impacts to waters of the U.S. including wetlands; and potential indirect and cumulative impacts.

A Coordination Plan will be prepared that addresses the project history, need and purpose, preliminary alternatives, and project schedule. A letter that describes the proposed action and a request for comments will be sent to appropriate Federal, state, and local agencies, and to private organizations and citizens who have previously expressed interest in the proposal. In conjunction with the Feasibility Study completed in June 2003, TxDOT developed a public involvement plan, sponsored three citizens' advisory committee (CAC) meetings, held two public meetings, and distributed two newsletters. Initial agency and public scoping meetings were held in June 2005 and May 2007. A new public involvement program will be developed that includes a project mailing list, project Web site, project newsletters, new agency and public scoping meetings, CAC and Technical Advisory Committee, and informal meetings with interested citizens and stakeholders. In addition, a public hearing will be held after the publication of the draft EIS. Public notice will be given of the time and place of the hearing. The draft EIS will be available for public and agency review and comment prior to the public hearing.

A public and agency scoping meeting will be held at the TxDOT Corpus Christi District Office—Training Center, 1701 S. Padre Island Drive, Corpus Christi, TX 78416, by TxDOT on August 9, 2011 to provide an opportunity for participating agencies, cooperating agencies, and the public to be involved in review and comment on the draft Coordination Plan, defining the need and purpose for the proposed project, determining the range of alternatives for consideration in the draft EIS, and establishing methodologies to evaluate alternatives. TxDOT will publish notice in general circulation newspapers in the project area at least 30 days prior to the meeting, and again approximately 10 days prior to the meeting.

To ensure that the full range of issues related to this proposed action is addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

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

Issued on: June 16, 2011.

Gregory S. Punske,

District Engineer, Austin, Texas.

[FR Doc. 2011–15577 Filed 6–21–11; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Action on Proposed Highway in Illinois

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for judicial review of actions by FHWA and other Federal agencies.

SUMMARY: This notice announces actions taken by the FHWA and other Federal agencies that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to the proposed Illinois Route 336 (IL 336) highway project, for construction of an access-controlled, four-lane expressway on new right-of-way between the proposed Macomb Bypass in McDonough County, passing through Fulton County to Interstate 474 (I–474) on the west side of Peoria in Peoria County, Illinois. Those actions

grant licenses, permits and approvals for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions of the highway project will be barred unless the claim is filed on or before December 19, 2011. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Mr. Norman R. Stoner, P.E., Division Administrator, Federal Highway Administration, 3250 Executive Park Drive, Springfield, Illinois 62703, Phone: (217) 492–4600, E-mail address: *Norman.Stoner@fhwa.dot.gov.* The FHWA Illinois Division Office's normal business hours are 7:30 a.m. to 4:15 p.m. You may also contact Mr. Joseph E. Crowe, P.E., Illinois Department of Transportation, Deputy Director of Highways, Region Three Engineer, 401 Main Street, Peoria, Illinois 61602, Phone: (309) 671–3333. The Illinois Department of Transportation Region Three's normal business hours are 8 a.m. to 4:30 p.m.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA and other Federal agencies have taken final agency actions by issuing licenses, permits and approvals for the following highway project in the State of Illinois: Construction of an approximately 60-mile, access-controlled, four-lane expressway on new right-of-way between the proposed Macomb Bypass in McDonough County, passing through Fulton County to Interstate 474 (I–474) on the west side of Peoria in Peoria County, Illinois. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Impact Statement (FEIS) for the project approved on March 3, 2011, the Record of Decision (ROD) issued on June 14, 2011, and other documents in the FHWA administrative record. The FEIS, ROD and other documents in the FHWA administrative record are available by contacting FHWA or the Illinois Department of Transportation at the addresses above. Project information can be viewed and downloaded from the project Web site *http://www.dot.il.gov/il336/default.aspx.* The FEIS can also be downloaded from *http://www.dot.il.gov/desenv/env.html,* or hard copies of the FEIS and the ROD are available upon request.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including, but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351] Federal-Aid Highway Act [23 U.S.C. 109].
2. *Air:* Clean Air Act [42 U.S.C. 7401–7671(q)].
3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303].
4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536]; Migratory Bird Treaty Act [16 U.S.C. 703–712].
5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archaeological and Historic Preservation Act (AHPA) [16 U.S.C. 469–469(c)].
6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)-2000(d)(1)]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].
7. *Wetlands and Water Resources:* Clean Water Act (Section 401 and 404) [33 U.S.C. 1251–1377]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287].
8. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898 Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations.

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

Authority: 23 U.S.C. 139(l)(1).

Issued on: June 14, 2011.

Norman R. Stoner,

Division Administrator, Springfield, Illinois.

[FR Doc. 2011–15576 Filed 6–21–11; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption From the Vehicle Theft Prevention Standard; Nissan

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition for exemption.

SUMMARY: This document grants in full Nissan North America, Inc.'s, (Nissan) petition for exemption of the Leaf vehicle line in accordance with 49 CFR part 543, *Exemption from Vehicle Theft Prevention Standard.* This petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541). Nissan requested confidential treatment of specific information in its petition by letter dated February 4, 2011. The agency addressed Nissan's request for confidential treatment by letter dated April 27, 2011.

DATES: The exemption granted by this notice is effective beginning with the 2012 model year.

FOR FURTHER INFORMATION CONTACT: Ms. Deborah Mazyck, Office of International Policy, Fuel Economy and Consumer Programs, NHTSA, West Building, W43–443, 1200 New Jersey Avenue, SE., Washington, DC 20590. Ms. Mazyck's telephone number is (202) 366–4139. Her fax number is (202) 493–2990

SUPPLEMENTARY INFORMATION: In a petition dated March 2, 2010, Nissan requested an exemption from the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541) for the MY 2012 Nissan Leaf vehicle line. The petition requested an exemption from parts-marking pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention Standard,* based on the installation of an antitheft device as standard equipment for the entire vehicle line.

Under § 543.5(a), a manufacturer may petition NHTSA to grant an exemption for one vehicle line per model year. In its petition, Nissan provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the Leaf vehicle line. Nissan will install its passive transponder-based, electronic immobilizer antitheft device as standard equipment on its Leaf vehicle line beginning with MY 2012. Major components of the antitheft device will include an immobilizer control module (BCM), immobilizer antenna, security indicator light, electronic immobilizer and vehicle control module. Nissan will also install an audible and visible alarm system on the Leaf as standard equipment. Nissan stated that activation of the immobilization device occurs when the ignition is turned to the ''OFF'' position and all the doors are closed and locked through the use of the key or the remote control mechanism. Deactivation occurs when all the doors are unlocked with the key or remote

control mechanism. Nissan's submission is considered a complete petition as required by 49 CFR 543.7, in that it meets the general requirements contained in § 543.5 and the specific content requirements of § 543.6.

Nissan stated that the immobilizer device prevents normal operation of the vehicle without the use of a special key. Nissan further stated that incorporation of the theft warning alarm system in the device has been designed to protect the belongings within the vehicle and the vehicle itself from being stolen when the back door and all of the side doors are closed and locked. If any of the doors are unlocked through an inside door lock knob or any attempts are made to reconnect the device after it has been disconnected, the device will also activate the alarm. Nissan stated that upon alarm activation, the head lamps will flash and the horn will sound. Nissan stated that the alarm can only be deactivated by unlocking the driver's side door with the key or the remote control device. Additionally, Nissan has incorporated a ''Security'' indicator light in the vehicle which it states will provide a signal to inform the vehicle owner as to the status of the immobilizer device. When the ignition key is turned to the ''OFF'' position, the indicator light begins flashing to notify the operator that the immobilizer device is activated.

In addressing the specific content requirements of 543.6, Nissan provided information on the reliability and durability of the device. Nissan stated that its antitheft device is tested for specific parameters to ensure its reliability and durability. Nissan provided a detailed list of the tests conducted and believes that the device is reliable and durable since the device complied with its specified requirements for each test.

Nissan provided data on the effectiveness of the antitheft device installed on its Leaf vehicle line in support of the belief that its antitheft device will be highly effective in reducing and deterring theft. Nissan referenced the National Insurance Crime Bureau's data which it stated showed a 70% reduction in theft when comparing MY 1997 Ford Mustangs (with a standard immobilizer) to MY 1995 Ford Mustangs (without an immobilizer). Nissan also referenced the Highway Loss Data Institute's data which reported that BMW vehicles experienced theft loss reductions resulting in a 73% decrease in relative claim frequency and a 78% lower average loss payment per claim for vehicles equipped with an immobilizer. Additionally, Nissan stated that theft rates for its Pathfinder vehicle experienced reductions from model year (MY) 2000 to 2001 with implementation of the engine immobilizer device as standard equipment and further significant reductions subsequent to MY 2001. Specifically, Nissan noted that the agency's theft rate data for MY's 2001 through 2006 reported theft rates of 1.9146, 1.8011, 1.1482, 0.8102, 1.7298 and 1.3474 respectively for the Nissan Pathfinder.

In support of its belief that its antitheft device will be as effective as compliance with the parts-marking requirements in reducing and deterring vehicle theft, Nissan compared its device to other similar devices previously granted exemptions by the agency. Specifically, it referenced the agency's grant of a full exemption to General Motors Corporation for the Buick Riviera and Oldsmobile Aurora (58 FR 44872, August 25, 1993), and Cadillac Seville vehicle lines (62 FR 20058, April 24, 1997) from the parts-marking requirements of the theft prevention standard. Nissan stated that it believes that since its device is functionally equivalent to other comparable manufacturers' devices that have already been granted parts-marking exemptions by the agency such as the ''PASS–Key III'' device used on the 1997 Buick Park Avenue, the 1998 Cadillac Seville and the 2000 Cadillac DeVille, Pontiac Bonneville, Buick LeSabre and Oldsmobile Aurora lines, the reduced theft rates of the ''PASS–Key'' and 'PASS–Key II'' equipped vehicle lines and the advanced technology of transponder electronic security, the Nissan immobilizer device has the potential to achieve the level of effectiveness equivalent to the ''PASS–Key III device.

Based on the supporting evidence submitted by Nissan on the device, the agency believes that the antitheft device for the Leaf vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR 541). The agency concludes that the device will provide the five types of performance listed in § 543.6(a)(3): promoting activation; attracting attention to the efforts of unauthorized persons to enter or operate a vehicle by means other than a key; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.7(b), the agency grants a petition for exemption from the parts-marking requirements of part 541 either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541. The agency finds that Nissan has provided adequate reasons for its belief that the antitheft device for the Leaf vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541). This conclusion is based on the information Nissan provided about its device.

For the foregoing reasons, the agency hereby grants in full Nissan's petition for exemption for the Leaf vehicle line from the parts-marking requirements of 49 CFR part 541, beginning with the 2012 model year vehicles. The agency notes that 49 CFR part 541, Appendix A–1, identifies those lines that are exempted from the Theft Prevention Standard for a given model year. 49 CFR part 543.7(f) contains publication requirements incident to the disposition of all part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the Theft Prevention Standard.

If Nissan decides not to use the exemption for this line, it must formally notify the agency. If such a decision is made, the line must be fully marked according to the requirements under 49 CFR parts 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if Nissan wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Part 543.7(d) states that a part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the anti-theft device on which the line's exemption is based. Further, part 543.9(c)(2) provides for the submission of petitions ''to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in that exemption.''

The agency wishes to minimize the administrative burden that part 543.9(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting part 543 to require the submission of a

modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be *de minimis.* Therefore, NHTSA suggests that if the manufacturer contemplates making any changes, the effects of which might be characterized as *de minimis,* it should consult the agency before preparing and submitting a petition to modify.

Authority: 49 U.S.C. 33106; delegation of authority at 49 CFR 1.50.

Issued on: June 15, 2011.

Christopher J. Bonanti,

Associate Administrator for Rulemaking.

[FR Doc. 2011–15562 Filed 6–21–11; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 33 (Sub-No. 298X)]

Union Pacific Railroad Company—Abandonment Exemption—in Freeborn County, MN

Union Pacific Railroad Company (UP) filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments* to abandon a line of railroad, known as the Hartland Subdivision, between milepost 119.65 at Curtis, the point of connection with the Albert Lea Subdivision, and the end of UP ownership at milepost 107.0 near Hartland, a distance of 12.65 miles, in Freeborn County, MN. The line traverses United States Postal Service Zip Codes 56007 and 56042.

UP has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7(c) (environmental report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on July 22, 2011, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by July 5, 2011. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by July 12, 2011, with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to UP's representative: Mack H. Shumate, Jr., Senior General Attorney, 101 North Wacker Drive, Room 1920, Chicago, IL 60606.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

UP has filed a combined environmental and historic report that addresses the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by June 27, 2011. Interested persons may obtain a copy of the EA by writing to OEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling OEA at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), UP shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by UP's filing of a notice of consummation by June 22, 2012, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: June 17, 2011.

By the Board.

Rachel D. Campbell,

Director, Office of Proceedings.

Andrea Pope-Matheson,

Clearance Clerk.

[FR Doc. 2011–15594 Filed 6–21–11; 8:45 am]

BILLING CODE 4915–01–P

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each OFA must be accompanied by the filing fee, which is currently set at $1,500. *See* 49 CFR 1002.2(f)(25).

DEPARTMENT OF THE TREASURY

Executive Office for Asset Forfeiture; Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Executive Office for Asset Forfeiture within the Department of the Treasury is soliciting comments concerning the Request for Transfer of Property Seized/Forfeited by a Treasury Agency, TD F 92–22.46.

DATES: Written comments should be received on or before August 19, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to the Department of the Treasury, Executive Office for Asset Forfeiture, Attn: Jackie A. Jackson, 1341 G Street, 9th Floor, NW., Washington, DC 20005. Telephone: (202) 622–2755. E-Mail Address: *Jackie.Jackson_@_Treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to the Department of the Treasury, Executive Office for Asset

Forfeiture, Attn: Jackie A. Jackson, 1341 G Street 9th Floor NW., Washington, DC 20005. Telephone: (202) 622–2755. E-Mail Address: *Jackie.Jackson_@_Treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Request for Transfer of Property Seized/Forfeited by a Treasury Agency, TD F 92–22.46.

OMB Number: 1505–0152.

Form Number: TD F 92–22.46.

Abstract: The form was developed to capture the minimum amount of data necessary to process the application for equitable sharing benefits. Only one form is required per seizure. If a law enforcement agency does not make this one time application for benefits under the equitable sharing process, the agency will not benefit from the forfeiture process.

Current Actions: This is a notice for the continued use of the established form. There are several changes to the form or instructions. Type of Review: Extension (with changes).

Proposed Changes: A line will be added to collect the financial and budgetary contact name, telephone number and e-mail address. This information will be used for future payment notification purposes. Under Section VII. Certifications: A line will be added to collect the printed name of the requester. A line will be added to collect the printed name of the legal counsel. Section VI Title changed to: Summary of Agency Participation (and explanation of items in prior section as necessary). Official use question moved from section IV. to section III. New wording as follows: Is this a non-monetary asset that will be placed into official use? Yes No. In order to create a revised form the overall formatting of the document will be changed.

Affected Public: Federal, State and local law enforcement agencies participating in the Treasury asset sharing program.

Estimated Number of Respondents: 5,000.

Estimated Time per Respondent: 30 Minutes.

Estimated Total Annual Burden Hours: 2,500.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Eric E. Hampl,

Director, Department of the Treasury, Executive Office for Asset Forfeiture.

[FR Doc. 2011–15607 Filed 6–21–11; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form W–2G

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form W–2G, Certain Gambling Winnings.

DATES: Written comments should be received on or before August 22, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins, at (202) 622–6665, or at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet, at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Certain Gambling Winnings.

OMB Number: 1545–0238.

Form Number: Form W–2G.

Abstract: Internal Revenue Code sections 6041, 3402(q), and 3406 require payers of certain gambling winnings to withhold tax and to report the winnings to the IRS. IRS uses the information to verify compliance with the reporting rules and to verify that the winnings are properly reported on the recipient's tax return.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations, state or local governments, and non-profit institutions.

Estimated Number of Responses: 4,104,771.

Estimated Time Per Response: 19 min.

Estimated Total Annual Burden Hours: 1,272,479.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 16, 2011.

Allan Hopkins,

Tax Analyst.

[FR Doc. 2011–15563 Filed 6–21–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Notice and Request for Comments

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). The IRS is soliciting comments concerning information collection requirements related to Branded Prescription Drug Sales—Dispute Resolution Process for 2011 Preliminary Fee Calculation.

DATES: Written comments should be received on or before August 22, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this revenue procedure should be directed to Allan Hopkins, at (202) 622–6665, or at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet, at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Application Requirements, Retroactive Reinstatement and Reasonable Cause under Section 6033(j).

OMB Number: 1545–2209.

Notice Number: Revenue Procedure 2011–24.

Abstract: This revenue procedure establishes a dispute resolution process for the preliminary fee calculation for the 2011 annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs. The fee was enacted by section 9008 of the Patient Protection and Affordable Care Act (ACA), Public Law 111–148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Public Law 111–152 (124 Stat. 1029 (2010)). All references in this revenue procedure to section 9008 are references to section 9008 of the ACA, as amended by section 1404 of HCERA.

Current Actions: There are no changes being made to the burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business of other for-profit organizations.

Estimated Number of Respondents: 119.

Estimated Average Time Per Respondent: 40 hours.

Estimated Total Annual Burden Hours: 4,760.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless the collection displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 16, 2011.

Allan Hopkins,

Tax Analyst.

[FR Doc. 2011–15565 Filed 6–21–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8801

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8801, Credit For Prior Year Minimum Tax—Individuals, Estates and Trusts.

DATES: Written comments should be received on or before August 22, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to, Yvette B. Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to, Joel Goldberger (202) 927–9368, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *Joel.P.Goldberger@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Credit For Prior Year Minimum Tax—Individuals, Estates and Trusts.

OMB Number: 1545–1073.

Form Number: 8801.

Abstract: Form 8801 is used by individuals, estates, and trusts to compute the minimum tax credit, if any, available from a tax year beginning after 1986 to be used in the current year or to be carried forward for use in a future year.

Current Actions: There are no changes being made to Form 8801 at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 12,914.

Estimated Total Annual Burden Hours: 93,756.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal

revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 8, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–15567 Filed 6–21–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8453–F and Form 8879–F

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8453–F, U.S. Estate of Trust Income Tax Declaration and Signature for Electronic and Magnetic Made Filing and Form 8879–F, IRS e-file Signature Authorization for Form 1041.

DATES: Written comments should be received on or before August 22, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Joel Goldberger at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 927–9368 or through the Internet at *Joel.Goldberger.irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: U.S. Estate of Trust Income Tax Declaration and Signature for Electronic and Magnetic Media Filing.

OMB Number: 1545–0967.

Form Numbers: 8453–F.

Abstract: This form is used to secure taxpayer signatures and declarations in conjunction with electronic or magnetic media filing of trust and fiduciary income tax returns, Form 8453–F, together with the electronic or magnetic media transmission, will comprise the taxpayer's income tax return (Form 1041).

Title: IRS e-file Signature Authorization for Form 1041.

OMB Number: 1545–0967.

Form Number: 8879–F.

Abstract: This form has been created to provide e-file signature authorization for Form 1041 to foster IRS policy promoting e-filing of returns. The form is necessary to support modernized e-file initiatives. This form will reduce paper processing and handling of forms 1041, schedule K–1 (Form 1041), and related forms and schedules.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

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

Estimated Number of Respondents: 2,000.

Estimated Time per Respondent: 53 minutes.

Estimated Total Annual Burden Hours: 1,750.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 7, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–15568 Filed 6–21–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 4797

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 4797, Sales of Business Property.

DATES: Written comments should be received on or before August 22, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Joel Goldberger, at (202) 927–9368, or at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224,

or through the Internet, at *Joel.P.Goldberger@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Sales of Business Property.

OMB Number: 1545–0184.

Form Number: 4797.

Abstract: Form 4797 is used by taxpayers to report sales, exchanges, or involuntary conversions of assets used in a trade or business. It is also used to compute ordinary income from recapture and the recapture of prior year losses under section 1231 of the Internal Revenue Code.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

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

Estimated Number of Respondents: 1,993,957.

Estimated Time per Respondent: 53 hr., 1 min.

Estimated Total Annual Burden Hours: 100,633,248.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 7, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–15571 Filed 6–21–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Forms 1042, 1042–S, and 1042–T

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1042, Annual Withholding Tax Return for U.S. Source Income of Foreign Persons, Form 1042–S, Foreign Person's U.S. Source Income Subject to Withholding, and Form 1042–T, Annual Summary and Transmittal of Forms 1042–S.

DATES: Written comments should be received on or before August 22, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Joel Goldberger, at (202) 927–9368, or at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *Joel.P.Goldberger@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Form 1042, Annual Withholding Tax Return for U.S. Source Income of Foreign Persons, Form 1042–S, Foreign Person's U.S. Source Income Subject to Withholding, and Form 1042–T, Annual Summary and Transmittal of Forms 1042–T.

OMB Number: 1545–0096.

Form Numbers: 1042, 1042–S, and 1042–T.

Abstract: Form 1042 is used by withholding agents to report tax withheld at source on payment of certain income paid to nonresident alien individuals, foreign partnerships, or foreign corporations. The IRS uses this information to verify that the correct amount of tax has been withheld and paid to the United States. Form 1042–S is used to report certain income and tax withheld information to nonresident alien payees and beneficial owners. Form 1042–T is used by withholding agents to transmit Forms 1042–S to the IRS.

Current Actions: There is no change to the forms previously approved by the OMB. However, due to an increase in the estimated number of responses, there is an increase in the paperwork burden previously approved by OMB. We are requesting an increase in the burden hours of 1,376,594. This form is being submitted for renewal purposes only.

Type of Review: This is a revision of a currently approved collection.

Affected Public: Business or other for profit organizations and individuals or households.

The burden estimate is as follows:

	Number of responses	Time per response	Total hours
Form 1042	36,400	18.05	657,020
Form 1042–S	3,525,300	.58	2,044,674
Form 1042–T	19,500	.20	3,900
	3,581,200	.....	2,705,594

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection

of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 7, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–15573 Filed 6–21–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 5305A–SEP

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 5305A–SEP, Salary Reduction Simplified Employee Pension-Individual Retirement Accounts Contribution Agreement.

DATES: Written comments should be received on or before August 22, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Joel Goldberger, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202), 927–9368, or through the Internet at *Joel.P.Goldberger@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Salary Reduction Simplified Employee Pension-Individual Retirement Accounts Contribution Agreement.

OMB Number: 1545–1012.

Form Number: 5305A–SEP.

Abstract: Form 5305A–SEP is used by an employer to make an agreement to provide benefits to all employees under a Simplified Employee Pension (SEP) described in Internal Revenue Code section 408(k). This form is not to be filed with the IRS, but is to be retained in the employer's records as proof of establishing a SEP and justifying a deduction for contributions made to the SEP.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals.

Estimated Number of Respondents: 100,000.

Estimated Time per Respondent: 9 hours, 43 minutes.

Estimated Total Annual Burden Hours: 972,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103. *Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 7, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–15574 Filed 6–21–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1099–DIV

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1099–DIV, Dividends and Distributions.

DATES: Written comments should be received on or before August 22, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–6665, or through the Internet at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Dividends and Distributions.

OMB Number: 1545–0110.

Form Number: 1099–DIV.

Abstract: Form 1099–DIV is used by the IRS to insure that dividends are

properly reported as required by Internal Revenue Code section 6042, that liquidation distributions are correctly reported as required by Code section 6043, and to determine whether payees are correctly reporting their income.

Current Actions: Two line items were deleted.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Responses: 111,922,150.

Estimated Time per Response: 18 minutes.

Estimated Total Annual Burden Hours: 34,695,867.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 16, 2011.

Allan Hopkins,

Tax Analyst.

[FR Doc. 2011–15575 Filed 6–21–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning requirements respecting the adoption or change of accounting method; extensions of time to make elections.

DATES: Written comments should be received on or before August 22, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Allan Hopkins, at (202) 622–6665, or at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet, at *Allan.M.HopkinsAirs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Requirements Respecting the Adoption or Change of Accounting Method; Extensions of Time to Make Elections.

OMB Number: 1545–1488. *Regulation Project Number:* REG–209837–96.

Abstract: This final regulation provides the procedures for requesting an extension of time to make certain elections, including changes in accounting method and accounting period. In addition, the regulation provides the standards that the IRS will use in determining whether to grant taxpayers extensions of time to make these elections.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of currently approved collection.

Affected Public: Business or other for-profit organizations, individuals, not-for-profit institutions, and farms.

Estimated Number of Respondents: 500.

Estimated Time Per Respondent: 10 hours.

Estimated Total Annual Burden Hours: 5,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 16, 2011.

Allan Hopkins,

IRS Reports Clearance Officer.

[FR Doc. 2011–15564 Filed 6–21–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information

collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). The IRS is soliciting comments concerning information collection requirements related to methods to determine taxable income in connection with a cost sharing arrangement.

DATES: Written comments should be received on or before August 22, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to, Yvette B. Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this regulation should be directed to Joel Goldberger, (202) 927–9368, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *Joel.P.Goldberger@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Methods to Determine Taxable Income in Connection with a Cost Sharing Arrangement.

OMB Number: 1545–1364.

Regulation Project Number: REG–144615–02 (T.D. 9441).

Abstract: The collection of information related to the IRS's assessment of whether a cost sharing arrangement is valid, and whether each participant's share of costs is proportionate to the participants share of benefits, and whether arm's length compensation has been paid to those participants providing external contributions such that an appropriate return is provided to those participants for putting their funds at risk to a greater extent than the other participants.

This document contains temporary regulations that provide further guidance and clarification regarding methods under section 482 to determine taxable income in connection with a cost sharing arrangement in order to address issues that have arisen in administering the current regulations. The temporary regulations affect domestic and foreign entities that enter into cost sharing arrangements described in the temporary regulations. The text of these temporary regulations also serves as the text of the proposed regulations set forth in the Proposed Rules section in the issue of the **Federal Register** dated January 5, 2009, (74 FR 340).

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 500.

Estimated Total Annual Burden Hours: 9,350.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 14, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–15566 Filed 6–21–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). The IRS is soliciting comments concerning information collection requirements related to Instructions for Requesting Rulings and Determination Letters.

DATES: Written comments should be received on or before August 22, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of regulation should be directed to Joel Goldberger, (202) 927–9368, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *Joel.P.Goldberger@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Instructions for Requesting Rulings and Determination Letters.

OMB Number: 1545–0819.

Regulation Project Number: T.D. 9006.

Abstract: This document contains final regulations relating to the notice to interested parties requirement. Before the IRS can issue an advance determination regarding the qualification of a retirement plan, a plan sponsor must provide evidence that it has notified all persons who qualify as interested parties that an application for an advance determination will be filed with the IRS. These regulations set forth standards by which a plan sponsor may satisfy the notice to interested parties requirement. The final regulations affect retirement plan sponsors, plan participants and other interested parties with respect to a determination letter application, and certain representatives of interested parties.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: All Taxpayers.

Estimated Number of Respondents: 271,914.

The estimated annual burden per respondent varies from 15 minutes to 1 hour, depending on individual circumstances, with an estimated average of 55 minutes.

Estimated Total Annual Burden Hours: 248,496.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to

respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 13, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–15569 Filed 6–21–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Application and Termination Notice for Municipal Securities Dealer Principal or Representative

AGENCY: Office of Thrift Supervision (OTS), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The proposed information collection request (ICR) described below has been submitted to the Office of Management and Budget (OMB) for review and approval, as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3507. OTS is soliciting public comments on the proposal.

DATES: Submit written comments on or before July 22, 2011. A copy of this ICR, with applicable supporting documentation, can be obtained from *RegInfo.gov* at *http://www.reginfo.gov/public/do/PRAMain.*

ADDRESSES: Send comments, referring to the collection by title of the proposal or by OMB approval number, to OMB and OTS at these addresses: Office of Information and Regulatory Affairs, *Attention:* Desk Officer for OTS, U.S. Office of Management and Budget, 725 17th Street, NW., Room 10235, Washington, DC 20503, or by fax to (202) 393–6974; and Information Collection Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, by fax to (202) 906–6518, or by e-mail to *infocollection.comments@ots.treas.gov.* OTS will post comments and the related index on the OTS Internet Site at *http://www.ots.treas.gov.* In addition, interested persons may inspect comments at the Public Reading Room, 1700 G Street, NW., Washington, DC 20552 by appointment. To make an appointment, call (202) 906–5922, send an e-mail to *public.info@ots.treas.gov,* or send a facsimile transmission to (202) 906–7755.

FOR FURTHER INFORMATION CONTACT: For further information or to obtain a copy of the submission to OMB, please contact Ira L. Mills at, *ira.mills@ots.treas.gov*, or on (202) 906–6531, or facsimile number (202) 906–6518, Regulations and Legislation Division, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: OTS may not conduct or sponsor an information collection, and respondents are not required to respond to an information collection, unless the information collection displays a currently valid OMB control number. As part of the approval process, we invite comments on the following information collection.

Title of Proposal: Application and Termination Notice for Municipal Securities Dealer Principal or Representative.

OMB Number: 1550–0123.

Form Numbers: MSD–5 and MSD–4.

Description: Section 15B(a)(2) of the Securities Exchange Act of 1934 (Act) requires, in part, that municipal securities dealers notify their appropriate regulatory agency (ARA) of their activities. This information is required to satisfy the requirements of the Act. The Financial Services Regulatory Relief Act of 2006 provides for the inclusion of the OTS in the definition of an ARA for federal savings associations (FSAs).

The forms are completed by certain FSA employees that act as municipal securities dealer principals or representatives, and are submitted to OTS. OTS reviews the information to monitor registered persons' entry into, and exit from, municipal securities dealer activities. The information contributes to the OTS's understanding of the FSA and helps to facilitate the supervision of the municipal securities dealer activities.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 14.

Estimated Frequency of Response: On occasion.

Estimated Total Burden: 11 hours.

Clearance Officer: Ira L. Mills, (202) 906–6531, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

Dated: June 15, 2011.

Ira L. Mills,

Paperwork Clearance Officer, Office of Chief Counsel, Office of Thrift Supervision.

[FR Doc. 2011–15472 Filed 6–21–11; 8:45 am]

BILLING CODE 6720–01–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Mutual Holding Company

AGENCY: Office of Thrift Supervision (OTS), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The proposed information collection request (ICR) described below has been submitted to the Office of Management and Budget (OMB) for review and approval, as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3507. OTS is soliciting public comments on the proposal.

DATES: Submit written comments on or before July 22, 2011. A copy of this ICR, with applicable supporting documentation, can be obtained from RegInfo.gov at *http://www.reginfo.gov/public/do/PRAMain.*

ADDRESSES: Send comments, referring to the collection by title of the proposal or by OMB approval number, to OMB and OTS at these addresses: Office of Information and Regulatory Affairs, Attention: Desk Officer for OTS, U.S. Office of Management and Budget, 725 17th Street, NW., Room 10235, Washington, DC 20503, or by fax to (202) 393–6974; and Information Collection Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, by fax to (202) 906–6518, or by e-mail to *infocollection.comments@ots.treas.gov.* OTS will post comments and the related index on the OTS

Internet Site at *http://www.ots.treas.gov.* In addition, interested persons may inspect comments at the Public Reading Room, 1700 G Street, NW., Washington, DC 20552 by appointment. To make an appointment, call (202) 906–5922, send an e-mail to *public.info@ots.treas.gov,* or send a facsimile transmission to (202) 906–7755.

FOR FURTHER INFORMATION CONTACT: For further information or to obtain a copy of the submission to OMB, please contact Ira L. Mills at, *ira.mills@ots.treas.gov,* or on (202) 906–6531, or facsimile number (202) 906–6518, Regulations and Legislation Division, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: OTS may not conduct or sponsor an information collection, and respondents are not required to respond to an information collection, unless the information collection displays a currently valid OMB control number. As part of the approval process, we invite comments on the following information collection.

Title of Proposal: Mutual Holding Company.

OMB Number: 1550–0072.

Form Numbers: MHC–1 (OTS Form 1522) and MHC–2 (OTS Form 1523).

Description: The OTS analyzes the submitted information to determine whether the applicant meets the statutory and regulatory criteria to form a mutual holding company and/or perform minority stock issuances. Information provided in the notice or application is essential if the OTS is to fulfill its mandate to prevent insider abuse and unsafe and unsound practices by mutual holding companies and their subsidiaries. Minority issuances are not feasible without an application process that includes the review of such information.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 50.

Estimated Frequency of Response: On occasion.

Estimated Total Burden: 4,132 hours.

Clearance Officer: Ira L. Mills, (202) 906–6531, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

Dated: June 15, 2011.

Ira L. Mills,

Paperwork Clearance Officer, Office of Chief Counsel, Office of Thrift Supervision.

[FR Doc. 2011–15471 Filed 6–21–11; 8:45 am]

BILLING CODE 6720–01–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Amendment of a Federal Savings Association Charter

AGENCY: Office of Thrift Supervision (OTS), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The proposed information collection request (ICR) described below has been submitted to the Office of Management and Budget (OMB) for review and approval, as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3507. OTS is soliciting public comments on the proposal.

DATES: Submit written comments on or before July 22, 2011. A copy of this ICR, with applicable supporting documentation, can be obtained from RegInfo.gov at *http://www.reginfo.gov/public/do/PRAMain.*

ADDRESSES: Send comments, referring to the collection by title of the proposal or by OMB approval number, to OMB and OTS at these addresses: Office of Information and Regulatory Affairs, Attention: Desk Officer for OTS, U.S. Office of Management and Budget, 725 17th Street, NW., Room 10235, Washington, DC 20503, or by fax to (202) 393–6974; and Information Collection Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, by fax to (202) 906–6518, or by e-mail to *infocollection.comments@ots.treas.gov.* OTS will post comments and the related index on the OTS Internet Site at *http://www.ots.treas.gov.* In addition, interested persons may inspect comments at the Public Reading Room, 1700 G Street, NW., Washington, DC 20552 by appointment. To make an appointment, call (202) 906–5922, send an e-mail to *public.info@ots.treas.gov,* or send a facsimile transmission to (202) 906–7755.

FOR FURTHER INFORMATION CONTACT: For further information or to obtain a copy of the submission to OMB, please contact Ira L. Mills at, *ira.mills@ots.treas.gov,* or on (202) 906–6531, or facsimile number (202) 906–6518, Regulations and Legislation Division, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: OTS may not conduct or sponsor an information collection, and respondents are not required to respond to an information collection, unless the information collection displays a currently valid OMB control number. As part of the approval process, we invite comments on the following information collection.

Title of Proposal: Amendment of a Federal Savings Association Charter.

OMB Number: 1550–0018.

Form Number: N/A.

Description: The charter of an insured Federal savings association is a formal document created when a savings association establishes its corporate existence. The charter states the scope, purpose and duration for the corporate entity. Also, for a Federally chartered savings association, the charter confirms that the board of directors has formally committed the institution to Section 5 of the Home Owners' Loan Act (''HOLA'') and other applicable statutes and regulations governing federally chartered savings associations. *See* 12 U.S.C. 1464.

All Federally chartered savings associations are required to file charter amendment applications or notices with OTS. OTS Regional Office staff review the applications and notices to determine whether the charter amendments comply with the regulations and OTS policy.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 1.

Estimated Frequency of Response: On occasion.

Estimated Total Burden: 6 hours.

Clearance Officer: Ira L. Mills, (202) 906–6531, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

Dated: June 15, 2011.

Ira L. Mills,

Paperwork Clearance Officer, Office of Chief Counsel, Office of Thrift Supervision.

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21 CFR Part 1141

Required Warnings for Cigarette Packages and Advertisements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA–2010–N–0568]

RIN 0910–AG41

Required Warnings for Cigarette Packages and Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to add a new requirement for the display of health warnings on cigarette packages and in cigarette advertisements. This rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that requires FDA to issue regulations requiring color graphics, depicting the negative health consequences of smoking, to accompany the nine new textual warning statements required under the Tobacco Control Act. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act (FCLAA) to require each cigarette package and advertisement to bear one of nine new textual warning statements. This final rule specifies the color graphic images that must accompany each of the nine new textual warning statements.

DATES: This rule is effective September 22, 2012. See section VIII of this document, *Implementation Date,* for additional information. The incorporation by reference of a certain publication listed in the rule is approved by the Director of the Federal Register as of September 22, 2012.

FOR FURTHER INFORMATION CONTACT: Gerie Voss or Kristin Davis, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 877–287–1373, *gerie.voss@fda.hhs.gov* or *kristin.davis@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
A. Purpose and Overview
B. Background
II. Need for the Rule and Responses to Comments
A. Cigarette Use in the United States and the Resulting Health Consequences
1. Smoking Prevalence and Initiation in the United States
2. Health Consequences of Smoking
B. Inadequacy of Existing Warnings
C. Consumers' Lack of Knowledge of the Health Risks
D. Larger, Graphic Warnings Communicate More Effectively
E. Need To Refresh Required Warnings
III. FDA's Selection of Color Graphic Images
A. Methodology for Selecting Images
B. FDA's Research Study
1. Study Design
2. Use of FDA's Study Results in Selection of Images
3. Comments on FDA's Research Study
C. Comments to the Docket
1. Comments Submitting Research on FDA's Proposed Required Warnings
2. Other Comments
D. Selected Images
1. ''WARNING: Cigarettes are addictive''
2. ''WARNING: Tobacco smoke can harm your children''
3. ''WARNING: Cigarettes cause fatal lung disease''
4. ''WARNING: Cigarettes cause cancer''
5. ''WARNING: Cigarettes cause strokes and heart disease''
6. ''WARNING: Smoking during pregnancy can harm your baby''
7. ''WARNING: Smoking can kill you''
8. ''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers''
9. ''WARNING: Quitting smoking now greatly reduces serious risks to your health''
10. Image for Advertisements With a Small Surface Area
E. Non-Selected Images
1. ''WARNING: Cigarettes are addictive''
2. ''WARNING: Tobacco smoke can harm your children''
3. ''WARNING: Cigarettes cause fatal lung disease''
4. ''WARNING: Cigarettes cause cancer''
5. ''WARNING: Cigarettes cause strokes and heart disease''
6. ''WARNING: Smoking during pregnancy can harm your baby''
7. ''WARNING: Smoking can kill you''
8. ''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers''
9. ''WARNING: Quitting smoking now greatly reduces serious risks to your health''
10. Image for Advertisements With a Small Surface Area
IV. Comments Regarding Textual Warning Statements
A. Changes to Textual Warning Statements
B. Attribution to the Surgeon General
C. Foreign Language Translations
V. Description of the Final Rule
A. Overview of the Final Rule
B. Description of Final Regulations and Responses to Comments
1. Section 1141.1—Scope
2. Section 1141.3—Definitions
3. Section 1141.10—Required Warnings
4. Section 1141.12—Incorporation by Reference of Required Warnings
5. Section 1141.14—Misbranding of Cigarettes
6. Section 1141.16—Disclosures Regarding Cessation
VI. Comments Regarding Implementation Issues
A. Technical Issues Regarding Compliance
B. Textual Statement Color Formats
C. Random Display and Rotation of Warnings
VII. Legal Authority and Responses to Comments
A. FDA's Legal Authority
B. First Amendment Commercial Speech Issues
C. Takings Under the Fifth Amendment
VIII. Implementation Date
IX. Federalism
X. Environmental Impact
XI. Analysis of Impacts
A. Introduction and Summary
B. Comments on the Preliminary Regulatory Impact Analysis
1. General
2. Need for the Rule
3. Benefits
4. Costs
5. Distributional Effects
6. Impact on Small Entities
C. Need for the Rule
D. Benefits
1. Reduced Cigarette Smoking Rates
2. Quantifying Benefits That Accrue to Dissuaded Smokers
3. Reduced Fire Costs
4. Summary of Benefits
E. Costs
1. Number of Affected Entities
2. Costs of Changing Cigarette Labels
3. Ongoing Costs of Equal and Random Display
4. Market Testing Costs Associated With Changing Cigarette Package Labels
5. Advertising Restrictions: Removal of Noncompliant Point-of-Sale Advertising
6. Government Administration and Enforcement Costs
7. Summary of Costs
F. Cost-Effectiveness Analysis
G. Distributional Effects
1. Tobacco Manufacturers, Distributors, and Growers
2. National and Regional Employment Patterns
3. Retail Sector
4. Advertising Industry
5. Excise Tax Revenues
6. Government-Funded Medical Services, Insurance Premiums, and Social Security
H. International Effects
I. Regulatory Alternatives
1. 24-Month Compliance Period
2. 6-Month Compliance Period
3. Alternative Graphic Images
4. Summary of Regulatory Alternatives
J. Impact on Small Entities
1. Description and Number of Affected Small Entities
2. Description of the Potential Impacts of the Final Rule on Small Entities
3. Alternatives to Minimize the Burden on Small Entities
XII. Paperwork Reduction Act of 1995
XIII. References

I. Introduction

A. Purpose and Overview

The Tobacco Control Act was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FCLAA, and providing FDA with the authority to regulate tobacco products (Pub. L. 111–31; 123 Stat.

1776). Section 201 of the Tobacco Control Act modifies section 4 of FCLAA (15 U.S.C. 1333) to require that the following nine new health warning statements appear on cigarette packages and in cigarette advertisements:

- WARNING: Cigarettes are addictive
- WARNING: Tobacco smoke can harm your children
- WARNING: Cigarettes cause fatal lung disease
- WARNING: Cigarettes cause cancer
- WARNING: Cigarettes cause strokes and heart disease
- WARNING: Smoking during pregnancy can harm your baby
- WARNING: Smoking can kill you
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers
- WARNING: Quitting smoking now greatly reduces serious risks to your health.

Section 201 of the Tobacco Control Act also states that ''the Secretary [of Health and Human Services] shall issue regulations that require color graphics depicting the negative health consequences of smoking'' to accompany the nine new health warning statements.

As discussed in the preamble to the proposed rule (75 FR 69524 at 69525, November 12, 2010), cigarette smoking kills an estimated 443,000 Americans each year, most of whom began smoking when they were under the age of 18 (Ref. 1). Tobacco use is the foremost preventable cause of premature death in the United States, and has been shown to cause cancer, heart disease, lung disease, and other serious adverse health effects (Ref. 2). The U.S. Government has a substantial interest in reducing the number of Americans, particularly children and adolescents, who use cigarettes and other tobacco products in order to prevent the life-threatening health consequences associated with tobacco use (section 2(31) of the Tobacco Control Act).

Although FCLAA has required the inclusion of textual health warnings on cigarette packages and in cigarette advertisements for many years, there is considerable evidence, which was presented in the preamble to the proposed rule (75 FR 69524 at 69529 through 69531) and is discussed in section II.B of this document, that the existing cigarette health warnings are given little attention or consideration by viewers. A 2007 report from the Institute of Medicine (IOM) described the warnings as ''invisible'' (Ref. 3), and found that they fail to communicate relevant information in an effective way. The warnings currently in use in the United States also fail to include any graphic component, despite the evidence in the scientific literature that larger, graphic health warnings promote greater understanding of the health risks of smoking and would help to reduce consumption (*see* 75 FR 69524 at 69531 through 69533). In proposing this regulation and preparing this final rule, we found substantial evidence indicating that larger cigarette health warnings including a graphic component, like those being required in this rule, would offer significant health benefits over the existing warnings. Consistent with Executive Order 13563, this regulation is ''based on the best available evidence'' and has allowed ''for public participation and an open exchange of ideas.''

B. Background

On November 12, 2010, as directed by section 201 of the Tobacco Control Act and in the interest of public health, we issued a proposed rule seeking to modify the warnings that appear on cigarette packages and in cigarette advertisements to include color graphic images depicting the negative health consequences of smoking; these images were proposed to accompany the nine new textual warning statements set forth in section 201 of the Tobacco Control Act (*see* 75 FR 69524). The Agency received more than 1,700 comments to the docket for the November 12, 2010, notice of proposed rulemaking (NPRM) on required warnings for cigarette packages and advertisements. Comments were received from cigarette manufacturers, retailers and distributors, industry associations, health professionals, public health or other advocacy groups, academics, State and local public health agencies, medical organizations, individual consumers, and other submitters. These comments are summarized and responded to in the relevant section(s) of this document. Similar comments are grouped together by the topics discussed or the particular portions of the NPRM or codified language to which they refer.

To make it easier to identify comments and FDA's responses, the word ''Comment,'' in parenthesis, appears before the comment's description, and the word ''Response,'' in parenthesis, appears before FDA's response. Each comment is numbered to help distinguish among different comments. Similar comments are grouped together under the same comment number. 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.

II. Need for the Rule and Responses to Comments

A. Cigarette Use in the United States and the Resulting Health Consequences

1. Smoking Prevalence and Initiation in the United States

In explaining the need for the proposed rule, we provided information in the NPRM on smoking prevalence and initiation rates among adults and children in the United States. As stated in the NPRM (75 FR 69524 at 69526), approximately 46.6 million U.S. adults (or 20.6 percent of the adult population) are cigarette smokers (Ref. 4). Moreover, almost half (46.3 percent) of youth in grades 9 through 12 in the United States have tried cigarette smoking, and 19.5 percent of youth in grades 9 through 12 are current cigarette smokers (Ref. 5 at p. 10). Smoking rates among U.S. adults have shown virtually no change during the 5-year period from 2005 to 2009 (Ref. 4), and smoking rates among U.S. youth have not decreased from 2006 to 2009 (Ref. 6).

Furthermore, each year millions of U.S. adults and children become new smokers. Data from the 2008 National Survey on Drug Use and Health indicate that 2.4 million persons aged 12 or older in the United States smoked cigarettes for the first time in the past 12 months (Ref. 7 at p. 59). In addition, these data indicate that almost 1 million Americans aged 12 or older started smoking cigarettes daily within the past 12 months (Ref. 7 at p. 60).

In other words, approximately 6,600 people aged 12 or older in the United States become new cigarette smokers every day, and more than 2,500 individuals become new daily cigarette smokers every day (Ref. 7 at pp. 59–60). Moreover, nearly 4,000 of the people who become new cigarette smokers every day and nearly 1,000 of the individuals who become new daily cigarette smokers every day are children under the age of 18 (Ref. 7 at pp. 59–60). These statistics for youth smokers are particularly concerning, as studies suggest that the age people start smoking can greatly influence how much they smoke per day and how long they smoke, which in turn influences their risk of tobacco-related disease and death (Refs. 8, 9, and 10).

FDA received many comments that were strongly supportive of the proposed rule, some of which provided data and information consistent with that in the NPRM regarding cigarette use prevalence and initiation in the United States (75 FR 69524 at 69526 through 69527). Many of these comments also stated that smokers would be more

likely to quit smoking and that nonsmokers would be less likely to start smoking if cigarette advertisements and packages display, visually and graphically, the health effects of cigarettes. Most of these comments expressed a belief that the required warnings would help reduce the existing and future use of cigarettes. Some comments that were supportive of the proposed rule discussed the smoking prevalence and initiation rates in the United States in particular populations. These comments, and FDA's responses, are summarized in the following paragraphs.

(Comment 1) Multiple comments indicated that people with less education and lower incomes have higher smoking prevalence rates in general. One comment from a health care association indicated that women of low educational background have higher smoking prevalence rates and that many of these women still are not aware of cigarettes' impact on life expectancy, heart disease, and pregnancy.

(Response) We agree that adults with low education levels have higher than average smoking prevalence rates. For example, as discussed in the NPRM (75 FR 69524 at 69526), 49.1 percent of adults with a General Education Development certificate (GED) and 28.5 percent of adults with less than a high school diploma were current smokers in 2009, compared with 5.6 percent of adults with a graduate degree (Ref. 4). We also agree that graphic health warnings may be particularly important communication tools for these smokers, as there is evidence suggesting that countries with graphic health warnings demonstrate fewer disparities in health knowledge across educational levels (Ref. 11 at p. 18 and Ref. 3 at p. 295).

(Comment 2) Multiple comments noted that smoking rates vary by race and ethnicity, with American Indians/Alaska Natives having the highest rates. One comment also noted that the health and economic costs of smoking vary by race and ethnicity. For example, the comment stated that African-American smokers suffer disproportionately from smoking-related diseases, including lung cancer, heart disease, and strokes (*citing* Ref. 12), and called for measures to address these disparities.

One comment from a State public health agency indicated that racial minority populations and economically disadvantaged populations have smoking prevalence rates that are two to three times higher than the general population.

(Response) We agree that smoking rates vary by race and ethnicity and socioeconomic status. For example, prevalence data from 2009 for current U.S. adult cigarette smokers indicate that, among racial/ethnic groups, adults reporting multiple races had the highest smoking prevalence (29.5 percent), followed by American Indians/Alaska Natives (23.2 percent) (Ref. 4). We also agree that economically disadvantaged populations have higher smoking prevalence rates. For example, data from 2009 indicate that the prevalence of current smoking was higher among U.S. adults living below the Federal poverty level (31.1 percent) than among those at or above this level (19.4 percent) (*Id.*). We have selected required warnings that will help effectively convey the negative health consequences of smoking to a wide range of population groups, including different racial and ethnic groups and different socioeconomic groups, and that can help both to discourage nonsmokers from initiating cigarette use and to encourage current smokers to consider quitting. For additional information regarding our selection of required warnings to reach a broad range of population groups, see section III of this document regarding our selection of the final images.

(Comment 3) Multiple comments stated that tobacco use disparities exist among lesbian, gay, bisexual, and transgender individuals. One comment from a community organization stated that lesbian, gay, bisexual, and transgender individuals smoke at rates almost 50 percent to 200 percent higher than the rest of the population and strongly supported the proposed rule.

(Response) We agree that evidence suggests that gay, lesbian, bisexual, and transgender populations have higher smoking rates than their heterosexual counterparts (Ref. 13). The required warnings will help convey information about various health risks of smoking to individuals from a wide range of demographic groups and will help encourage smoking cessation and discourage smoking initiation.

(Comment 4) One comment from a nonprofit research organization indicated that members of the U.S. military have rates of smoking that are unacceptably high, particularly among younger members. The comment detailed the negative outcomes of smoking to military personnel, including lower physical performance, an increased risk of injury during physical tasks, a greater number of days sick and unable to report for duty, poorer job performance, and a higher likelihood of premature discharge from active duty, and stated that smoking and its negative effects among active duty personnel costs the military an estimated $1 billion annually in health care and lost productivity (Ref. 14). The comment also referred to evidence suggesting the tobacco industry has targeted military members and fought efforts to reduce tobacco product consumption by military personnel, and indicated that the proposed rule is an important step in protecting military members from the health harms of cigarette use and will likely decrease cigarette use among military personnel.

(Response) We agree that members of the U.S. military have higher smoking prevalence rates than the general population; approximately 20.6 percent of the U.S. adult population smoke cigarettes, while data from 2008 indicate that 31 percent of active duty military personnel smoke cigarettes (Ref. 15). We agree that the required warnings will help convey information about various health risks of smoking to a wide range of individuals, including members of the U.S. military and veterans who began smoking while in military service, and that the required warnings will encourage smoking cessation and discourage smoking initiation in these individuals.

2. Health Consequences of Smoking

Smoking is responsible for at least 443,000 premature deaths per year in the United States, and each year cigarettes are responsible for approximately 5.1 million years of potential life lost (Ref. 1). Annual direct health care expenses due to smoking total approximately $96 billion, and annual productivity losses due to premature deaths alone from cigarette smoking total approximately $96.8 billion (*Id.*).

The Agency received many comments that were supportive of the proposed rule, some of which reiterated the health risks of smoking described in the NPRM (75 FR 69524 at 69527 through 69529) and stressed the need for measures, such as graphic health warnings, to curb smoking in the United States in order to improve health and to reduce the massive health care costs attributable to tobacco-related illnesses. Some of these comments cited data demonstrating that smoking is the leading cause or most powerful risk factor for particular diseases, such as chronic obstructive pulmonary disease (COPD), bladder cancer, and atherosclerosis.

However, FDA also received multiple comments disputing the health risks of smoking. These comments and FDA's responses are summarized in the following paragraphs.

(Comment 5) One comment from an individual expressed a belief that addiction to nicotine is 99 percent

psychological and only 1 percent pharmacological, and that nicotine is no more addictive than caffeine.

(Response) We disagree with the assertion that nicotine addiction does not have a substantial physiologic component. While we acknowledge that behavioral processes play a role in initiation and maintenance of nicotine addiction, nicotine is a powerful pharmacologic agent that acts in a variety of ways at different sites in the body. As stated in the NPRM, nicotine causes physical dependence characterized by withdrawal symptoms that usually accompany nicotine abstinence (75 FR 69524 at 69528). Regarding the relative addictiveness of nicotine and caffeine, caffeine is distinct from nicotine in its abuse liability, which includes a consideration of multiple factors, including the dependence potential of a substance and the degree to which it produces adverse effects (*see* Ref. 16 at p. 304). Caffeine produces only minimal disruptive physiological effects and, unlike nicotine from tobacco products, caffeine is generally not used in ways that are considered to be of significant adverse health effect (*see Id.* at pp. 285 and 304).

(Comment 6) One comment stated that nicotine withdrawal is the only medical condition that is irrefutably caused by cigarettes.

(Response) We disagree with this comment. While nicotine addiction is one negative health effect of cigarette smoking, it is not the only medical condition irrefutably caused by cigarettes. As detailed in the 2004 report of the Surgeon General, ''The Health Consequences of Smoking,'' which summarizes thousands of peer-reviewed scientific studies and was itself peer-reviewed, cigarettes have been shown to cause an ever-expanding number of diseases and conditions, including lung cancer, laryngeal cancer, oral cavity and pharyngeal cancers, esophageal cancer, bladder cancer, pancreatic cancer, kidney cancer, stomach cancer, cervical cancer, acute myeloid leukemia, all the major clinical cardiovascular diseases, COPD, and a range of acute respiratory illnesses (Ref. 2).

Maternal smoking during pregnancy causes a reduction in lung function in infants, and women who smoke during pregnancy are more likely to experience premature rupture of the membranes, placenta previa, and placental abruption (*Id.* at pp. 508 and 576). Smoking also increases rates of preterm delivery and shortened gestation, and women who smoke are twice as likely as nonsmokers to have low birth weight infants; smoking also increases the risk of sudden infant death syndrome (SIDS) (*Id.* at pp. 569, 576, 587 and 601).

Children who smoke experience impaired lung growth and an early onset of lung function decline (*Id.* at pp. 508–509, 2004 SG). Smoking during adulthood also leads to a premature onset of accelerated age-related decline in lung function (*Id.* at p. 509). Smoking also results in poor asthma control and causes a range of respiratory symptoms in children, adolescents, and adults, including coughing, phlegm, wheezing, and shortness of breath (*Id.*).

Furthermore, cigarette smokers have poorer overall health status compared to nonsmokers, and an increased risk of adverse surgical outcomes related to wound healing and respiratory complications compared to nonsmokers. Smokers are also at an increased risk for hip fractures, and smoking increases the risk for periodontitis, cataract, and the occurrence of peptic ulcer disease in persons who are *Heliobacter pylori* positive (*Id.* at pp. 717–719, 736, 777, 780, and 813).

In addition, exposure to secondhand smoke has been shown to cause a variety of negative health effects in nonsmokers, including lung cancer, cardiovascular disease, and respiratory symptoms (*see* Ref. 17).

(Comment 7) Some comments were submitted by individuals disputing the negative health consequences of smoking that are described in the graphic warnings. These comments generally indicated that the individuals submitting the comments were smokers, and that they and/or their family members (who were exposed to secondhand smoke) had not experienced negative health effects from smoking.

(Response) We disagree with these comments. Cigarette smoking has been shown to cause a wide range of negative health consequences, as detailed in the previous response. Furthermore, it can be years before some of the negative health consequences of smoking clinically manifest. Thus, the personal health status of the individuals submitting these comments could change in the future. A scientific determination that a product causes a particular negative health consequence is based on data from large groups of individuals, and the fact that an individual product user has not experienced (or has not yet experienced) a particular negative health consequence does not mean the product does not cause that harm.

Moreover, to the extent these comments indicate that many smokers do not fully understand the serious health risks of cigarettes or do not believe that these risks apply to them, they illustrate the need for health warnings that effectively communicate the negative health consequences of smoking to consumers. For additional information regarding consumers' lack of knowledge of smoking risks, see section II.C of this document.

(Comment 8) One comment stated that cigarettes are a minor public health concern compared to obesity and alcohol, and that cigarette use results in less health care costs than medical treatment for the obese.

(Response) As discussed in the NPRM, cigarette smoking is the leading cause of preventable death and disease in the United States (Ref. 4). Furthermore, cigarettes are responsible for health care expenditures and productivity losses resulting in a combined economic burden of approximately $193 billion per year (Ref. 1). The total costs of smoking to society are much higher, as the estimate for productivity losses does not include costs associated with smoking-related disability, employee absenteeism, or costs associated with secondhand-smoke attributable disease morbidity and mortality (*Id.*).

We disagree that cigarettes are a minor public health concern, even as compared to other public health issues, and also disagree with the implication that the public health issue of smoking should not be addressed because other public health issues exist. The required warnings will have a significant, positive impact on public health (75 FR 69524 at 69526), and as a result will help mitigate the single largest cause of preventable death and disease in the United States.

B. Inadequacy of Existing Warnings

In the preamble to the proposed rule, FDA explained how cigarette packages and advertisements can be effective channels for communication of important health information, particularly given that pack-a-day smokers are potentially exposed to warnings more than 7,000 times per year (75 FR 69524 at 69529). However, the existing warnings have suffered from three crucial problems: (1) They have not changed in more than 25 years, (2) they often go unnoticed, and (3) they fail to convey relevant information in an effective manner. FDA also explained that larger, graphic warnings communicate the health risks of smoking more effectively. The preamble to the proposed rule presented extensive evidence from other countries' experiences with graphic warnings as well as information from the 2007 IOM Report (75 FR 69524 at 69531). On the

basis of the available scientific evidence, the IOM concluded that larger, graphic warnings would promote greater public knowledge of the health risks of using tobacco and would help reduce consumption (Ref. 3).

We received numerous comments regarding the adequacy of the existing warnings that appear on cigarette packages and advertisements. The large majority of these comments supported our analysis of the existing warnings, but a few comments disagreed with this analysis. These comments, and our responses, are summarized in the following paragraphs.

(Comment 9) A substantial number of comments, including those from health institutions, nonprofit organizations, academics, and consumers, agreed with FDA's conclusion that the existing warnings that appear on cigarette packages and advertisements are ineffective at conveying the health risks of smoking (75 FR 69524 at 69529 through 69531).

However, one comment stated that the current warnings were ''fine.'' Two comments expressed the belief that the existing warnings have worked successfully in the current information environment.

(Response) We disagree with the comments stating that the existing warnings that appear on cigarette packages and advertisements are effective. As several other comments noted, the Surgeon General has long recognized that the cigarette warnings are deficient. For example, in its 1994 report the Surgeon General noted that the warnings had become ineffective due to their size, shape, and familiarity (Ref. 18). That same year, the IOM concluded that the warnings were ''inadequate * * * and woefully deficient when evaluated in terms of proper public health criteria'' (Ref. 19 at p. 237). Yet those same warnings are still in use more than 16 years after the Surgeon General's report and 26 years after their inception. Accordingly, we conclude that the existing warnings for cigarettes do not adequately communicate the health risks of smoking.

C. Consumers' Lack of Knowledge of the Health Risks

In the preamble to the proposed rule, FDA described how the existing warnings that currently appear on cigarette packages and advertisements have largely gone unnoticed by both smokers and nonsmokers (75 FR 69524 at 69530). FDA also provided clear evidence that the warnings have failed to convey appropriately crucial information such as the nature and extent of the health risks associated with smoking cigarettes (75 FR 69524 at 69530 through 69531).

FDA received many comments regarding the level of consumers' knowledge regarding the health risks of smoking. Several comments stated that consumers are adequately informed about the risks of smoking or even overestimate the risks of smoking, while many other comments explained that consumers lack knowledge about a wide variety of smoking risks. A summary of these comments, and our responses, is included in the following paragraphs.

(Comment 10) Several comments, including comments from tobacco product manufacturers and individual consumers, objected to the new required warnings, in part because they claimed that consumers already know the health risks associated with smoking. The submitters expressed the belief that the new warnings are unnecessary, because the new warnings provide information that the public has been aware of for many years.

(Response) We disagree. Many comments provided significant evidence to support the notion that consumers, including those in communities with low literacy rates and military personnel, actually lack knowledge or underestimate the risks associated with smoking. As discussed in this document, this lack of knowledge may involve either an incomplete understanding of the statistical risks or a failure to understand the personal (as opposed to the statistical) risks (*see also* section XI.B.2 of this document). There is also a possibility that the risks are not considered at the time of purchase, even if they are understood—a special problem for those who are deciding whether to start to smoke. The requirements adopted here should help to counteract all of these problems.

While most smokers understand that smoking poses certain statistical risks to their health, many fail to appreciate the severity and magnitude of those risks (Refs. 20 and 21), and there is evidence that even when smokers appreciate the statistical risk, they underestimate the personal risk that they face (Ref. 22). A 2007 survey found that two in three smokers underestimate the chance of a smoker developing lung cancer compared to a nonsmoker (Ref. 23). The survey also found that up to a third of smokers erroneously believe that certain activities, such as exercise and taking vitamins, could ''undo'' most of the effects of smoking (*Id.*).

Other research also highlights how smokers underestimate the health effects of smoking. For example, in a 2008 survey, more than one-quarter of current smokers did not agree that smoking increases a person's chances of getting cancer ''a lot'' (Ref. 24). Furthermore, one study, involving smokers' perception of their personal risk, found that only 40 percent of current smokers believed they had a higher-than-average risk of cancer and only 29 percent believed they had a higher-than-average risk of heart disease (Ref. 25). Even among heavy smokers (those who smoke at least 40 cigarettes per day), less than half believed they were at increased risk for these diseases (*Id.*). In another demonstration of underestimation of personal risk, a study found that adolescent smokers underestimated their personal risk, even if they had an accurate sense of the statistical risk (Ref. 22).

A 2005 study of smokers in the United States and three other countries found that there were significant gaps in smokers' knowledge about the risks of smoking and that smokers living in countries where health warnings referred to specific disease consequences of smoking were much more likely to be aware of those consequences (Ref. 26). The study concluded that smokers are not fully informed about the risks of smoking, and that warnings that are graphic, larger, and more comprehensive in content are more effective in communicating the health risks of smoking (*Id.*).

Thus, even if consumers are aware of certain negative health consequences of smoking, such as lung cancer and emphysema, and even if they are aware of certain statistical risks, many smokers underestimate their personal risks, and many Americans are under-informed about other health risks associated with smoking. For example, while nearly all daily smokers in one study correctly identified that smoking caused lung cancer (99 percent) and emphysema (97 percent), a lower percentage of respondents correctly identified smoking as causing low birth weight babies (88 percent), worsened asthma (85 percent), miscarriages (76 percent), other cancers (69 percent), head and neck cancers (68 percent), cervical cancer (48 percent), stomach ulcers (46 percent), reproductive difficulties (44 percent), osteoporosis (41 percent), and SIDS (40 percent) (Ref. 27). In fact, research indicates that most people know only one or two of the many diseases causes by smoking. One survey found that while a majority of people knew that smoking caused life-threatening illnesses, more than half of the respondents were unable to name a smoking-related illness other than lung cancer (Ref. 28). Similarly, researchers

found that when asked about health risks of smoking, 39 percent of respondents either answered incorrectly or said they did not know (Ref. 29).

Americans also lack adequate understanding of the addictive nature of cigarettes. Although one comment provided local surveys showing that adults already know that cigarettes are addictive, there is also evidence that many adolescents do not appreciate the addictive nature of cigarettes. The 2007 IOM Report explained that ''adolescents misperceive the magnitude of smoking harms and the addictive properties of tobacco and fail to appreciate the long-term dangers of smoking, especially when they apply the dangers to their own behavior'' (Ref. 3 at p. 93). In addition, one survey found that fewer than 5 percent of daily smokers in high school think that they still will be smoking at all in 5 years, yet more than 60 percent of high school smokers are regular daily smokers 7 to 9 years later (Ref. 30). Another survey found that only 7.4 percent of adult smokers and 4.8 percent of young smokers expected to smoke longer than 5 years when they started, but 87 percent of these adults and 76 percent of these youth reported that they had been smoking for more than 5 years (Ref. 31).

There is also evidence that certain demographic groups are even less aware of the negative health consequences of smoking, which is particularly concerning in light of the evidence that these groups also have some of the highest smoking prevalence rates (*see* section II.A.1 of this document). For example, research shows that knowledge of smoking risks is lower among people with lower incomes and fewer years of education (Refs. 32 33 and 24). Smokers in the military also underestimate the actual risk of serious disease and substantially underestimate their own risks (a point that fits well with the evidence of underestimation of personal risks) (Refs. 34 35 and 36).

In addition to underestimating the risks smoking poses to their own health, Americans underestimate the health effects of secondhand smoke on others. In the 2010 Report, ''How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease,'' the Surgeon General concluded that ''many of the effects from active smoking can be observed in persons involuntarily exposed to cigarette smoke'' (Ref. 37). In addition, individual studies have shown that secondhand smoke triggers childhood asthma and is associated with both heart disease and cancer (Ref. 17). Yet, most parents believe that smoke exposure has little or no negative impact on children's asthma (Ref. 38), and a 2009 study found that nearly one-fifth of Americans do not believe that secondhand smoke is dangerous to nonsmokers (Ref. 39).

There is a final point. Even if many people do have an accurate understanding of the statistical risk, and even if, in the abstract, many smokers also have an accurate understanding of their personal risk, that understanding may be too abstract to be thought of at the time of purchase, especially (but not only) for those who are starting to smoke. Efforts to make the relevant risks salient are justified and indeed required under the Tobacco Control Act.

(Comment 11) A few comments claimed that adults actually overestimate the risks of smoking-related disease, and stated that this further underscores the lack of a need for graphic health warnings. In particular, one comment referred to a Montana survey in which adults believed that smoking caused colon cancer.

(Response) We disagree with these comments. While the Montana survey referred to in one of the comments indicates that some consumers are not aware of the precise relationship between smoking and certain diseases (for example, the 2004 Surgeon General's report notes that the evidence is suggestive but not sufficient to infer a causal relationship between smoking and colorectal cancer (Ref. 2 at p. 26)), we are aware of significant research indicating that many consumers are not sufficiently aware of the risks associated with smoking, as discussed in the previous response. We find that the weight of evidence clearly demonstrates that many consumers lack adequate knowledge about the health risks of smoking—especially the personal risks. In addition, the comments claiming that adults overestimate smoking's risks fail to take into account consumers' lack of knowledge of other health risks due to smoking, like the dangers of secondhand smoke, reproductive difficulties, and miscarriages, as described in the previous response.

D. Larger, Graphic Warnings Communicate More Effectively

Since Canada first introduced graphic health warnings for cigarettes in 2001, an extensive evidence base has been developed to examine the effects of graphic health warnings in Canada and in the more than 30 other countries that have adopted similar requirements for graphic health warnings on cigarettes. As FDA extensively discussed in the NPRM (75 FR 69524 at 69531 through 69533), the research literature indicates that large graphic health warnings, such as those being required in this rule, are more likely than text-only warnings to (1) get consumers' attention, (2) influence consumers' awareness of cigarette-related health risks, and (3) affect smoking intentions and behaviors. FDA received many comments on the efficacy of large, graphic warnings, as well as comments regarding the potential for any rebound effect from the use of graphic warnings. Those comments, and FDA's responses, are summarized in the following paragraphs.

(Comment 12) A wide variety of comments, including those from health institutions, nonprofit organizations, and academics, agreed with FDA's findings in the NPRM that larger, graphic warnings are effective.

However, several comments stated that the changes in the format and placement of the warnings being proposed, including the use of graphic images, will not result in reductions in cigarette use given the experiences in other countries. For example, one comment noted that Health Canada's own data found, among other things, that there was no statistically significant decline in smoking incidence consumption for adolescents or adults after the introduction of graphic warnings. This comment expressed the belief that Canada's warnings have been ineffective and that FDA's graphic health warnings will be similarly ineffective.

(Response) For the reasons stated in the NPRM, we conclude that larger, graphic warnings are effective in conveying the health risks of smoking, influencing consumer awareness of these risks, and affecting smoking intentions. We disagree with comments stating that the change in format and placement of the warnings will not be effective. The set of required warnings we have selected will satisfy our primary goal, which is to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements, and this effective communication can help both to discourage nonsmokers, including minor children, from initiating cigarette use and to encourage current smokers to consider cessation to greatly reduce the serious risks that smoking poses to their health.

The research literature clearly indicates that larger, graphic warnings are effective at communicating the health risks associated with smoking, encouraging users to quit smoking, and discouraging nonsmokers from beginning to smoke. We already included significant research to

substantiate this conclusion in the preamble to the proposed rule, and the comments did not specifically dispute this analysis (*see* 75 FR 69524 at 69531 through 69532). In addition, as we noted in the NPRM, the available evidence demonstrates that graphic health warnings are (1) more likely to be noticed than text-only warnings, (2) more effective for educating smokers about the health risks of smoking and for increasing the time smokers spend thinking about the health risks, and (3) associated with increased motivation to quit smoking (*Id.*). As several comments noted, evidence from countries with graphic health warnings also indicates that such warnings are an important information source for younger smokers, and that pictures are effective in conveying messages to children (Ref. 40 at pp. 3, 20, and 24–26). These important effects of graphic warnings are sustained longer than any impact from text-only warnings (Ref. 41).

Further, the data from Health Canada does not indicate that the warnings have been ineffective at conveying the health risks of smoking and impacting smoking intentions. We cited several studies in the preamble (including data from Health Canada) that illustrated the effectiveness of the Canadian graphic health warnings, which have been found effective at providing youth and adult smokers with health information, making consumers think about the health effects of smoking, and increasing smokers' motivations to quit smoking, among other things (*see* 75 FR 69524 at 69532). For example, national surveys conducted on behalf of Health Canada indicate that approximately 95 percent of youth smokers and 75 percent of adult smokers report that the Canadian pictorial warnings have been effective in providing them with important health information (Ref. 3 at p. 294).

(Comment 13) One comment suggested that the new required warnings will have a greater impact on nonsmokers who inadvertently view cigarette packages than on smokers and, therefore, will not be effective in achieving FDA's goals.

(Response) We are not aware of any evidence to substantiate this comment. Further, our required warnings are intended to have an impact on *both* smokers and nonsmokers. As stated in the preamble to the proposed rule, ''the new required warnings are designed to clearly and effectively convey the negative health consequences of smoking on cigarette packages and in cigarette advertisements, which would help both to discourage nonsmokers, including minor children, from initiating cigarette use and to encourage current smokers to consider cessation to greatly reduce the serious risks that smoking poses to their health'' (75 FR 69524 at 69526). Therefore, the warnings are intended to have an impact on nonsmokers as well as smokers, and the required warnings will effectively communicate the negative health consequences of smoking to both of these important audiences.

(Comment 14) Several comments, including comments from cigarette manufacturers and individual consumers, expressed concerns that the new required warnings on cigarette packages and advertisements would cause people not to look at packages or cause them to hold their cigarettes in decorative cases. The comments also indicated that some of the proposed images would induce youth to purchase cigarettes rather than deter them from smoking, because the new images would be striking to youth. These comments stated that this ''rebound effect'' would undermine the intent of the warnings and decrease their effectiveness.

(Response) We disagree. Comments expressing concerns about a potential rebound effect did not provide persuasive scientific evidence to demonstrate such an effect is likely to occur (or that it would have sufficient magnitude to be a significant concern). The comments referenced older studies that did not specifically address graphic warnings on cigarette packages and advertisements, and also referred to a qualitative study conducted on the European Union's graphic warnings, in which some focus group participants commented that some warnings were humorous or that they were not persuasive in educating consumers about dental diseases associated with smoking (Ref. 42). When weighing this qualitative information against the quantitative research available, including evidence from countries with graphic health warning requirements, as well as the findings of the expert panel of the IOM in its 2007 report (*see* Ref. 3), the information referenced in the comments is not persuasive. (While focus groups can provide useful information, it is well known that they are not as reliable as real-world evidence for drawing conclusions about causal relationships and generalizing results to the population as a whole (Ref. 43).)

Furthermore, we note that in the European Union qualitative study referenced in the comments, the researchers concluded that pictures have the potential to add a powerful element to health warning messages and that the old text-only messages were not working (Ref. 42 at p. 43). They also noted that some of the warning messages the comments referred to, including the referenced dental disease image, provoked a highly emotional response in all the countries surveyed despite the comments from certain focus group participants (*Id.* at p. 35). The research literature suggests that images that evoke emotional responses can increase the likelihood smokers will reduce their smoking, make an attempt to quit, or quit altogether (Ref. 44).

While one comment said that the failure of fear-inducing messages based on health effects is ''well-known in areas outside of smoking prevention,'' the comment did not provide sufficient evidence of such failure in the area of smoking prevention. In fact, as some comments discussed, there is scientific evidence relating to cigarette graphic health warnings illustrating the success of fear-inducing messages (*see, e.g.,* Ref. 44). For example, one comment referred to research that found that smokers exposed to Canada's graphic health warnings generally did not try to avoid the fear-inducing messages, and that any avoidance engaged in by smokers does not appear to undermine quitting intentions or attempts (*citing* Ref. 45). Similarly, researchers analyzing data related to graphic warnings found that:

> [T]here is no evidence that pictorial warnings lead to boomerang effects. An analysis of data from the ITC Four Country Survey found that the Australian pictorial warnings, introduced in 2005, led to greater avoidant behaviours (*e.g.* covering up the pack, keeping it out of sight, or avoiding particular labels), compared to Canada, the United Kingdom, and the USA. Importantly, those smokers who engaged in avoidant behaviours were no less likely to intend to quit or to attempt to quit replicating the findings of a study of the Canadian warnings. Thus, although pictorial warnings can lead to avoidance and defensive reactions, such reactions are actually indicators of positive impact.

(Ref. 46, *citing* Refs. 20 and 44). To the extent that smokers engage in any defensive avoidance with respect to the new required warnings, we are adding a reference to a cessation resource to give smokers an immediate way to act upon this impulse and access cessation assistance. The research literature suggests that such a reference is effective in diminishing potential avoidance effects in response to messages that arouse fear (*see* Ref. 40 at pp. 39–41). See section V.B.6 of this document for additional information regarding our rationale and authority for including a reference to a cessation resource in the required warnings.

(Comment 15) Several comments expressed concern about the potential

effectiveness of the new required warnings, particularly those that are fear-based, with certain portions of the population. These comments expressed the following concerns: (1) Many youths and young adults are rebellious and will be attracted to what they perceive as the ''forbidden fruit;'' (2) fear-based warnings fail with groups that have low self-esteem; (3) fear-based warnings fail with adolescents, because they tend not to be influenced by health-based deterrents; and (4) the new required warnings are ''high fear messages'' that may actually inhibit reductions in smoking, because they decrease a person's perceived ability to quit smoking. These comments expressed the belief that the new required warnings would be ineffective.

(Response) While acknowledging the concerns, we disagree. It is true that messages that induce fear, pointing to a risk, may not be effective when people are unaware of how to reduce the risk, but in this case, the best way to reduce the risk is clear. We have chosen a balanced set of images, including those that may arouse fear and those that may generate other emotional responses in certain individuals in order to reach a diverse population of smokers and nonsmokers, as well as youth, young adults, and adults. Furthermore, as is explained in more detail in section III.B of this document, we conducted a research study to quantitatively evaluate the relative efficacy of the proposed required warnings in communicating the health harms of smoking to adults (aged 25 or older), young adults (aged 18 to 24), and youth (aged 13 to 17). The nine selected required warnings showed positive effects on important study measures in all study populations, including youth, relative to the text-only control. In particular, as is discussed in more detail in section III of this document, the selected required warnings showed strong impacts on the salience measures in our research study, including emotional and cognitive measures.

The research literature suggests that these measures are likely to be related to behavior change. For example, the literature suggests that risk information is most readily communicated by messages that arouse emotional reactions (*see* Ref. 45), and that smokers who report greater negative emotional reactions in response to cigarette warnings are significantly more likely to have read and thought about the warnings and more likely to reduce the amount they smoke and to quit or make an attempt to quit (Ref. 44). The research literature also suggests that warnings that generate an immediate emotional response from viewers can confer negative feelings about smoking and undermine the appeal and attractiveness of smoking (Ref. 45 and Ref. 40 at pp. 37–38). In addition, research has shown that younger adolescents are more likely to notice and think about health warnings that include graphic images (Ref. 47).

The required warnings will effectively communicate the negative health consequences of smoking, and we do not agree that they will have unintended negative effects among younger population groups.

(Comment 16) One comment expressed concern that the new graphic images on cigarette packages and advertisements would actually make cigarette smokers sicker, as the images would increase smokers' anxiety and damage their self-esteem.

(Response) We disagree. We are not aware of any scientific evidence to support this claim. In fact, as discussed in the preamble to the proposed rule, the available evidence suggests that graphic health warnings can benefit the public health by increasing smokers' intentions to quit and reducing the likelihood of initiation by nonsmokers (75 FR 69524 at 69532).

(Comment 17) A few comments stated that fear-based warnings fail to work when the message being conveyed is already clearly understood and does not provide new information. These comments expressed the view that, because consumers already understand the risks associated with smoking, the new required warnings would not be effective in achieving FDA's goals.

(Response) We disagree. As explained in section II.C of this document, there is substantial evidence demonstrating that the premise of these comments is not correct and that many consumers do not adequately understand the personal risks associated with smoking.

E. Need To Refresh Required Warnings

As amended by the Tobacco Control Act, FCLAA includes provisions that can help prevent or delay the wear out of the new required warnings. For example, section 4(c)(1) of FCLAA (15 U.S.C. 1333(c)(1)) indicates that the required warnings on cigarette packages must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product, and be randomly distributed throughout the United States, in accordance with a warning plan approved by FDA. Section 4(c)(2) of FCLAA requires the warnings to be rotated quarterly in cigarette advertisements, also in accordance with a warning plan approved by FDA.

Nevertheless, as stated in the NPRM, we intend to monitor the effects of the new required warnings once they are put into use. We will conduct research and keep abreast of scientific developments regarding the efficacy of various required warnings and the types and elements of various warnings that improve efficacy. As stated in the NPRM, we will use the results of our monitoring and such research to help determine whether any of the textual warning statements or accompanying graphic images should be revised in a future rulemaking (75 FR 69524 at 69534). This commitment to continued empirical testing is consistent with Executive Order 13563, section 1, which states that our regulatory system ''must measure, and seek to improve, the actual results of regulatory requirements.''

FDA received numerous comments regarding the need periodically to refresh the warnings to minimize wear out, which we have summarized and responded to in the following paragraphs.

(Comment 18) Many comments, including comments from health institutions, nonprofit organizations, and academics, suggested that FDA should refresh the graphic warnings on a regular basis because consumers can become habituated to and ignore warnings. The comments referred to scientific research on the effectiveness of graphic warnings for cigarette packages and advertisements, which strongly recommends that warnings be periodically refreshed to maintain their effectiveness and impact on consumers (Refs. 18, 42, 44, and 26). The comments suggested a wide range of timeframes as to when FDA should refresh the graphic warnings. One comment suggested that FDA track the effectiveness of the required warnings on a quarterly basis and that the results of any testing be made publicly available. One comment suggested that FDA establish a conclusion that new graphic warnings for cigarette packages and advertisements will be required at no more than a 2-year interval. A few comments also suggested that FDA establish a target schedule for reconsideration and revision of the warnings, which would include ongoing consumer research and re-examination of the effectiveness of the required warnings.

(Response) We agree that refreshing the required warnings on a periodic basis can help maintain their effectiveness. Researchers have found that graphic images and text messages are likely to have greater impact at the time they are introduced and that

meaningful impact of the warnings may decline with repeated exposure (Ref. 41). Rotating a variety of cigarette warnings and updating the warnings periodically is likely to minimize the negative effects of overexposure (Ref. 3).

However, we are not aware of any research that warrants the selection of a particular timeframe for future iterations of required warnings. As stated by several comments, there is no definitive rate at which the warnings will wear out, as it depends on many factors including the variety of message executions, exposure level, and the appeal of the message.

We recognize the value of conducting ongoing evaluation of the effects of the required warnings after they enter the marketplace. We also intend to monitor and evaluate the effects of the required warnings, and to monitor the warnings for potential wear out. In addition, we will keep abreast of scientific developments regarding the efficacy of various required warnings and the types and elements of various warnings that improve efficacy. As noted, this monitoring is consistent with Executive Order 13563, which recognizes the importance of measuring ''actual results'' and of analyzing significant rules after they are in effect to determine whether they should be ''modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.''

When we determine that changes to the required warnings are appropriate (including changes to the textual warning statements and/or the color graphic images) because they would promote greater public understanding of the risks associated with smoking, we can exercise our authority to initiate a new rulemaking to modify the required warnings under section 202(b) of the Tobacco Control Act (adding subsection (d) to section 4 of FCLAA).[1]

III. FDA's Selection of Color Graphic Images

A. Methodology for Selecting Images

When we issued the NPRM, we proposed color graphic images to accompany the nine textual warning statements required by Congress in section 201 of the Tobacco Control Act. In all, we proposed 36 potential required warnings, consisting of the color graphic images FDA developed and the nine textual warning statements from the Tobacco Control Act. These 36 proposed required warnings were made available as electronic files in portable document format (.pdf) and displayed in the document entitled ''Proposed Required Warning Images,'' which was included in the docket for the proposed rule. The proposed required warnings were also made available on FDA's Web site. Consistent with section 4 of FCLAA, 2 versions of each of the 36 proposed required warnings were developed; one with the textual warning statement in black font on a white background, and one with the textual warning statement in white font on a black background.

As explained in the preamble to the proposed rule (75 FR 69524 at 69534 through 69535), in considering and developing appropriate color graphic images to accompany the nine textual warning statements set forth in section 201 of the Tobacco Control Act, FDA assessed the graphic warnings that other countries have required, and worked with various experts in the fields of health communications, marketing research, graphic design, and advertising to develop 36 proposed required warnings. Each of the proposed color graphic images depicted the negative health consequences of smoking, and the themes and subjects depicted in each image illustrated the message conveyed by the accompanying textual warning statement.

The NPRM explained that we planned to select 9 final required warnings from among the 36 proposed required warnings. We sought comments on what color graphic images to require in this final rule, including comments on the 36 proposed color graphic images included with the NPRM.

In addition, as is described in more detail in section III.B of this document, we conducted research on the 36 proposed required warnings to evaluate the relative effectiveness of the proposed color graphic images and their accompanying textual warning statements at conveying information about various health risks of smoking, and additionally, at encouraging smoking cessation and discouraging smoking initiation.

In order to determine which color graphic images to require in the final rule, we considered a number of factors. First, we considered the relative effectiveness of the proposed required warnings based on the strength of effect the different color graphic images had on the various endpoints and across the populations included in our study (see section III.B of this document for a more detailed description of the research study).

In addition, we considered the substantive public comments received in the docket related to the 36 proposed required warnings (see section III.C of this document for more information on the comments received; the comments relating to each image are summarized and responded to in sections III.D and III.E of this document). We also considered the comments received in the docket that suggested that we use other images in the required warnings, including images that have been used in other countries' graphic health warnings. However, as discussed in more detail in the following comment summaries and in section III.B of this document, we selected images for the nine required warnings from among the images we developed and proposed. Our research study, among other information, indicated these required warnings will effectively communicate the negative health consequences of smoking to a wide range of population groups. As explained in the comment responses throughout this section III, the comments submitted to the docket did not persuade us that other images, including images used in other countries' graphic health warnings, were more appropriate for use in the required warnings than the images we selected.

Furthermore, we considered the relevant scientific literature in the docket, and in particular the extent to which the literature supported or refuted aspects of the images and the extent to which the literature helped determine the appropriate weight to give to other information (including the appropriate weight to give to the various endpoints considered in our research study).

We also considered the variety and diversity reflected in the images in making selection decisions in order to ensure that the final set of required warnings effectively communicates risk information to a diverse range of audiences, including audiences that have been targeted by tobacco industry marketing efforts. We took into account the importance of selecting a set of required warnings that includes a diversity of styles (*e.g.,* photographic versus illustrative), themes, and human images (*e.g.,* race, gender, age). This is consistent with the evidence base for graphic health warnings from countries that have already implemented such warnings, which indicates that variety is important in enhancing the noticeability and salience of warnings and broadening their relevance for target groups (Ref. 40 at p. 46 and Ref. 48 at

[1] Section 202(b) of the Tobacco Control Act amends section 4 of FCLAA (15 U.S.C. 1333) to add a new subsection (d), ''Change in Required Statements.'' However, section 201 of the Tobacco Control Act also amends section 4 of FCLAA to add a new subsection (d), ''Graphic Label Statements.''

p. 9), and which suggests that warnings that include pictures of people should broadly represent the ethnic/racial profile of the relevant country (Ref. 11).

We also considered whether to have one image accompany each of the textual warning statements set forth in section 201 of the Tobacco Control Act.

We received multiple comments regarding our proposal to select 9 final required warnings and our proposal to select them from among the 36 proposed color graphic images that were made available with the NPRM. We have summarized and responded to these comments in the following paragraphs (we also received a number of comments on the proposed color graphic images themselves; these comments are summarized in sections III.D and III.E of this document. In addition, we received a number of comments regarding our research study, which assessed the relative effectiveness of the 36 proposed color graphic images; these comments are summarized in section III.C of this document).

(Comment 19) Several comments suggested that FDA select more than one graphic image for each new textual warning statement. The comments reasoned that by limiting the warnings to one graphic image per textual statement, the health warnings would effectively communicate to fewer segments of the smoking and nonsmoking populations. Some comments also suggested that selecting more than one image per warning statement would counteract wear out of the required warnings. One comment suggested that FDA develop multiple series of images and require that each series be used one at a time to delay wear out.

(Response) We decline to select more than one image for each warning statement as suggested in these comments. We believe that the set of nine required warnings we selected will be sufficient at this time to achieve our goal of effectively communicating the negative health consequences of smoking and to prevent wear out of the required warnings for several years. Furthermore, the nine selected required warnings will appeal to a diverse range of audiences, and, as discussed in section III.D of this document, the images selected showed significant effects on important measures in our research study across the three study populations (adults, young adults, and youth).

We intend to monitor the effects of these required warnings once they are put into use. We will conduct research and keep abreast of scientific developments regarding the efficacy of various required warnings and the types and elements of various warnings that improve efficacy. Given the significant changes being made to the text, format, and placement of the existing warnings by this rule, it will be valuable to obtain relevant data on the effects of the complete set of required warnings as soon as possible. If we were to expand the number of required warnings, it could delay an assessment of efficacy of the warnings under conditions of real-world use. We intend to use the results of our monitoring and of research conducted on the required warnings once they are in public use to determine whether changes should be made to the required warnings in a future rulemaking, including changes to add new images or to modify the existing required warnings. Accordingly, at this time we decline to select more than nine images.

(Comment 20) Multiple comments suggested that FDA use graphic warning images that have been tested or used in other countries instead of or in addition to one or more of the images that FDA proposed. Some of these comments indicated that images that are in use in other countries would be more effective and educational than some or all of FDA's proposed images.

(Response) We decline to follow this suggestion. FDA's research study evaluated the 36 proposed required warnings. The results from this research study suggest that the nine selected required warnings will effectively communicate negative health consequences of smoking to a diverse range of audiences. Moreover, if we were to select images that were not evaluated in our study, it would be difficult to objectively assess the relative efficacy of such images compared to the 36 proposed images. Compared to the information provided by our research study, the supporting information in the comments did not convince us that the images suggested by those comments would more effectively communicate the negative health consequences of smoking than the images we have selected in this final rule.

(Comment 21) A number of comments suggested that FDA use other images than those published with the proposed rule. For example, some comments recommended that FDA use images that depict real people with real diseases and not models. A few recommended that FDA include images that show negative cosmetic effects of smoking, such as stained fingers and bad breath, in order to impact adolescents concerned about body image. One comment suggested that FDA portray a picture of an obituary, while another recommended the use of an image depicting the amount of money smokers spend to purchase cigarettes every year.

(Response) We decline to select the images suggested in these comments. Each of the required warnings selected by FDA was quantitatively tested to assess its relative effectiveness in communicating the negative health consequences of smoking. In selecting the set of nine required warnings, we considered the results of our research study and a number of other factors and have concluded that the nine selected required warnings effectively communicate the negative health consequences of smoking. In addition, we are adopting the nine textual warning statements mandated by Congress in section 4(a)(1) of FCLAA. The images selected were designed to correlate with those warning statements; the available evidence base highlights the value of the text and images in graphic health warnings relating to one another in a meaningful way (*see* Ref. 40 at p. 41). Including images inconsistent with the textual warning statements could confuse consumers and detract from the effectiveness of the warnings. Furthermore, some of our selected images do show the negative cosmetic effects that can occur as a result of the health consequences of smoking. Moreover, some of the images proposed for use in the comments, such as an image showing the amount of money smokers spend to purchase cigarettes, would not be consistent with the statutory requirement that the required warnings depict the negative health consequences of smoking.

B. FDA's Research Study

As explained in the NPRM (75 FR 69524 at 69535), we conducted research on the 36 proposed required warnings. Specifically, we conducted an Internet-based consumer research study with over 18,000 participants that quantitatively examined the relative efficacy of the 36 proposed color graphic images in communicating the harms of smoking to 3 target groups: Adult smokers (age 25 or older), young adult smokers (aged 18 to 24), and youth (aged 13 to 17) who currently smoke or who are susceptible to smoking.

The purpose of the study was to: (1) Measure consumer attitudes, beliefs, and intended behaviors related to cigarette smoking in response to the proposed color graphic images and their accompanying textual statements; (2) determine whether consumer responses to the proposed color graphic images and their accompanying textual statements differed across various groups based on age, smoking status, or

other demographic variables; and (3) evaluate the relative effectiveness of the proposed color graphic images and their accompanying textual warnings statements at conveying information about various health risks of smoking, and additionally, at encouraging smoking cessation and discouraging smoking initiation.

We placed a report (Ref. 49; *see also* Ref. 50 [2]) that described the research study and presented the results of the analyses from the research study in the docket for the proposed rule and announced the report's availability by a notice in the **Federal Register** on December 7, 2010 (*see* 75 FR 75936 at 75936 through 75937) so that the public had an opportunity to comment on the results.

This section briefly describes the design of FDA's research study and key endpoints examined in the research study; a full description of the study and the several hundred pages of data and data analyses are contained in the study report and accompanying appendices (Ref. 49) that was placed in the docket for the proposed rule. This section also describes how the results from this research study informed the selection of the final required warnings.

FDA received numerous comments in the docket related to the research study; this section also includes a summary of the substantive comments received about the research study and FDA's responses to these comments.

1. Study Design

FDA's research study evaluated the required warnings proposed for each of the nine warning statements against a text-only control (which contained the warning statement without any accompanying color graphic image). Study participants were randomly assigned to be exposed to either one of the 36 proposed required warnings (treatment groups) or one of the 9 textual warning statements (control groups). Treatment groups for each target population (adults, young adults, and youth) viewed a hypothetical pack of cigarettes that included one of the proposed required warnings, which appeared on the upper 50 percent of the pack, while the control group viewed a hypothetical pack of cigarettes with a warning statement (but no warning image), which appeared on the side of the pack. Furthermore, among adults, an additional treatment group viewed a hypothetical advertisement that included one of the proposed required warnings, which encompassed approximately 20 percent of the upper right area of the advertisement, while a control group viewed a hypothetical advertisement with a warning statement in the same location (but without a warning image) that was presented using the size and format currently required by FCLAA. The study tested the relative efficacy of each proposed required warning relative to the text-only control for that warning statement for the various outcomes measured.

Each respondent viewed either a single cigarette package or advertisement that displayed one of the proposed required warnings or a text-only warning. Respondents answered questions about their immediate reactions to the cigarette package or advertisement, related attitudes and beliefs about smoking, as well as intentions to quit or start smoking. At the end of the survey, subjects were asked to recall which warning statement and image they saw earlier in the survey to assess the accuracy of recall. In addition, 1 week after completing the survey, subjects were re-contacted and asked to recall the warning statement and image to which they were exposed. Overall, the following key outcomes were measured after exposure to one of the required warnings or the text-only control, and/or at 1 week follow-up:

- Salience—The study examined emotional and cognitive responses to the cigarette packages and advertisements that bore health warnings. Participants provided ratings of their responses to the packages and advertisements. The ratings were aggregated to create two scales: (A) An emotional reaction scale, which included ratings on how the warning made the respondent feel, such as ''depressed,'' ''discouraged,'' and ''afraid''; and (B) a cognitive reaction scale, which included ratings on what the respondent thought about the warning, such as ''believable,'' ''meaningful,'' and ''convincing''.[3] Regression analyses were used to assess the relative impact of treatment conditions on ratings as compared to the text-only control.
- Recall—The study measured participants' recall of the nine warning statements after exposure to either one of the proposed required warnings or the text-only control (baseline). Participants were also re-contacted after 1 week and asked about their recall of the warning statement they had viewed (1 week follow-up). The results were analyzed to determine whether exposure to the proposed required warnings elicited higher recall of the warning statements than exposure to the text-only controls. In addition, in the treatment groups (*i.e.,* participants who viewed one of the proposed required warnings), recall of the image was assessed at baseline and at 1-week follow-up. Because the control group did not view an image, the impact of the proposed required warnings on image recall was measured against one of the proposed required warnings for each warning statement that had been selected to be the referent image and statistically assessing whether recall of the images associated with the other proposed required warnings was higher or lower than recall of the referent image.
- Influence on Beliefs—The study assessed whether the proposed required warnings had a significant impact on beliefs about the health risks of smoking to regular smokers relative to the text-only control, as well as whether they had a significant impact on beliefs about the health risks of secondhand smoke exposure to nonsmokers relative to the text-only control.
- Behavioral Intentions—The study assessed whether the proposed required warnings may have a significant impact on cessation, by assessing smokers' intentions to quit smoking (*i.e.,* asking participants how likely it is that they would try to quit smoking within the next 30 days). In youth, the study assessed whether the proposed required warnings may have a significant impact on potential initiation, using a measure of how likely youth felt they were to be smoking 1 year from now.

As the study report (Ref. 49) explains, the outcomes examined were selected based on established theories of message processing and health-related behavior change, which suggest that immediate emotional and cognitive reactions to messages, and recall of messages, are part of a process that eventually leads to

[2] While the numerical results reported in the study report (Ref. 49) were correct, and while all of the results discussed in this rule are accurately described, some of the descriptors contained in the study report were in error. An errata sheet for the study report (Ref. 50), which lists all the errors and the corrections, has been prepared and is being placed in the docket. These errors did not adversely impact commenters' ability to convey their assessment of the images and the study results in their comments. To the extent some comments included inaccurate statements about the study results in their significant comments as a result of the errors, we recognized the inaccuracy and were able to discern the material points in the comment and evaluate them appropriately, as is reflected in the comment summaries and responses.

[3] Some additional cognitive measures, including the reaction item ''the pack was difficult to look at'' (or, for the adult sample viewing the print ad, ''the ad was difficult to look at'') were also evaluated but were not reported as part of the composite cognitive reaction scale. These items were not sufficiently correlated with the other cognitive measures to include in the composite measure.

changes in beliefs and intentions and ultimately to behavior change.

2. Use of FDA's Research Study Results in Selection of Images

As described in section III.A of this document, in order to determine which color graphic images to require in the final rule, we considered a number of factors, including the results from our research study. We carefully examined the research results for the 36 proposed required warnings on all the different outcomes in determining which images to require in this final rule. However, the responses on the salience measures served as a primary basis for distinguishing among the 36 proposed required warnings for a number of reasons.

First, many of the proposed required warnings elicited significant impacts on the salience measures (emotional and cognitive measures), which the research literature suggests are likely to be related to behavior change (Ref. 51). For example, the literature suggests that risk information is most readily communicated by messages that arouse emotional reactions (*see* Ref. 45), and that smokers who report greater negative emotional reactions in response to cigarette warnings are significantly more likely to have read and thought about the warnings and more likely to reduce the amount they smoke and to quit or make an attempt to quit (Ref. 44). The research literature also suggests that warnings that generate an immediate emotional response from viewers can result in viewers attaching a negative affect to smoking (*i.e.,* feel bad about smoking), thus undermining the appeal and attractiveness of smoking (Ref. 45 and Ref. 40 at pp. 37–38).

In comparison to the salience measures, fewer of the proposed required warnings elicited significant impacts on the beliefs measures in our research study, and on the whole the proposed required warnings did not elicit strong responses on the intentions measures. Given the design of our research study, where participants had only a single exposure to one proposed required warning, it is not surprising that the proposed required warnings did not consistently show effects on these beliefs and intentions measures, which are more eventual outcomes in the behavior change process than the salience responses, which occur more immediately. However, this does limit the utility of these longer-term measures in discriminating across the proposed required warnings. Thus, given the design of the study, the results on the salience measures, which the research literature indicates are predictors of more eventual behavioral outcomes, were considered to be more meaningful than the results on the beliefs and intentions measures in discriminating between the images.

In addition, we gave greater weight to outcomes on the salience measures than to outcomes on the statement recall measures for several reasons. First, there is evidence to suggest that, while recall of associated warning message statements may be reduced in the short term by moderately or highly graphic pictorial warnings versus text-only controls or less graphic pictorial warnings, these warnings still increase intentions to quit through evoked emotional responses (Ref. 52). Second, as described previously, participants in the research study were exposed to a single viewing of the proposed required warnings, which does not allow for assessment of the effect that repetitive viewing of the required warnings may have on recall. Recall can be expected to increase in real world settings where consumers will be exposed to the warnings multiple times. Third, recall was generally high for all the proposed required warnings, even where there was not a significant difference compared to the text-only control or where recall was significantly lower for the proposed required warning than for the text-only control. For example, for the nine required warnings that we selected for use in this final rule, the research study shows that recall of both the textual warning statements and the color graphic images was high at both baseline and at 1-week follow-up, exceeding 50 percent on all measures, and, in many cases, exceeding 80 percent.

3. Comments on FDA's Research Study

FDA received a number of comments related to its research study in the docket for the proposed rule, which are summarized and responded to in the following paragraphs.

a. *Study design.* Several comments addressed the cross-sectional design of the study.

(Comment 22) Several comments, including comments from cancer researchers, nonprofit organizations, and academics noted that participants in the study were exposed to a proposed required warning only once in a controlled environment. These comments stated that the single exposure study design makes it impossible to assess long term or actual effects of the proposed required warnings. Two of these comments recommended that FDA conduct longitudinal research or post-market surveillance to assess actual long-term effects.

(Response) We agree that the study design does not permit us to reach firm conclusions about the long-term, real-world effects of the proposed required warnings on the measured outcomes. As noted previously, the purpose of the study was not to assess actual effects but to assess the relative effects of the proposed required warnings on various outcomes. Data on the relative effects of the various proposed required warnings provided a more objective and scientific basis to help select which required warnings should be included in the final regulation. A cross-sectional design with a single exposure under experimental conditions is appropriate for assessing relative effects. For absolute effects, the scientific literature presented in the preamble to the proposed rule provides a substantial basis for our conclusion that the required warnings will effectively communicate the health risks of smoking, thereby encouraging smoking cessation and discouraging smoking initiation.

However, we recognize the value of conducting an ongoing evaluation of the effects of the required warnings after they enter the marketplace, and we intend to monitor and evaluate their ability to effectively communicate the negative health consequences of smoking. This evaluation will provide information regarding whether the required warnings effectively reach the appropriate target audiences, wear out of the required warnings, and whether and what changes to the required warnings may be appropriate in any future rulemaking on this subject.

(Comment 23) A comment from tobacco product manufacturers stated that a longitudinal study demonstrating that the required warnings would have actual effects on smoking prevalence was necessary to support the final regulation.

(Response) We appreciate the value of longitudinal studies but disagree that such a study is necessary to support the final regulation. As discussed previously, our research study assessed the relative efficacy of the 36 proposed required warnings published with the NPRM, and the cross-sectional study design was appropriate for that purpose. The scientific literature presented in the preamble to the proposed rule provides a substantial basis for our conclusion that the required warnings will effectively communicate the health risks of smoking, thereby encouraging smoking cessation and discouraging smoking initiation.

(Comment 24) Several comments discussed behavioral models similar to that described in FDA's research study (*see* Ref. 49) and explained how those models provide a rationale for how health warnings can effectively communicate risk information about the harmful effects of tobacco use. For example, one comment from a researcher working on an international project to evaluate the impact of graphic health warnings for tobacco products stated that the primary objectives of health warnings are to educate and inform smokers and nonsmokers about the many negative health consequences of smoking and to provide information that can enhance their efficacy for quitting. The comment noted that effective health warnings increase knowledge and thoughts about the harms of cigarettes, the extent to which the smoker could personally experience a smoking-related disease, and as a result, increase motivation to quit smoking. Another academic who also is conducting research on graphic health warnings commented that a wide variety of research suggests that health warnings with pictures are significantly more likely to draw attention, result in greater information processing, and improve memory for warnings than text-only warnings. A comment from a researcher with expertise in risk perceptions and decisionmaking stated that changes in smoking behavior based on warning labels appear to require four steps: (1) Immediate, negative affective reactions to the potential consequences of smoking; (2) associations of these emotional reactions to smoking cues; (3) increases in perceptions of the risks of smoking, and finally (4) increases in quit contemplation and reductions in smoking behaviors.

(Response) We agree that the design of our research study is consistent with established social science models (in psychology, economics, and related fields) of risk communication and health behavior change. The purpose of graphic health warnings is to effectively communicate the negative health consequences of cigarette use to smokers and nonsmokers, which is critical given the seriousness of these consequences. Greater understanding of those health effects will motivate some smokers to stop smoking and prevent some nonsmokers from starting to smoke. The preamble to the proposed rule presented a detailed discussion of the scientific literature to substantiate our conclusion that graphic health warnings can be an effective means of communicating important health information about the risks of smoking (*see* 75 FR 69524 at 69531 through 69533). These comments provide additional support for that conclusion.

b. *Study results.* Several comments discussed the results from FDA's research study.

(Comment 25) Several comments, including comments from academics, nonprofit organizations, and health professional organizations, stated that FDA's research study provides data consistent with the overall literature demonstrating the effectiveness of graphic health warnings. For example, one comment stated that in general the study results are consistent with prior findings that the addition of graphic images to health warnings is beneficial in comparison to text-only warnings. Another comment stated that, based upon the FDA study and the existing scientific literature, it is possible to conclude that the proposed graphic warnings are likely to be effective.

Other comments, including comments from tobacco product manufacturers, advertising industry associations, and a public policy organization, asserted that FDA's research study fails to provide evidence of efficacy. These comments stated that the study did not show evidence that the proposed required warnings would actually affect prevalence of smoking, and failed to demonstrate sufficient evidence that the proposed required warnings would significantly affect consumer knowledge of the risks of smoking or actual behavior change.

(Response) We agree that the study is generally consistent with the existing scientific evidence demonstrating that graphic health warnings can effectively communicate the negative consequences of cigarette smoking, and by doing so, can encourage smoking cessation and discourage smoking initiation. We disagree that the study results do not support the efficacy of the warnings. We presented substantial research in the preamble to the proposed rule supporting the efficacy of graphic health warnings (75 FR 69524 at 69531 through 69534), and the results of our research study are consistent with that research.

c. *Study outcome measures.* Numerous comments discussed the key outcomes measured in FDA's research study.

(Comment 26) FDA received a wide variety of comments concerning the use of emotional reactions to assess the relative effectiveness of the proposed graphic warnings. A number of comments, including those from academics, medical institutions, and public health groups, supported the inclusion of emotional reaction measures. These comments stated that graphic health warnings that elicit strong emotional reactions, especially negative feelings, are more effective in communicating the negative health consequences of smoking and in motivating healthier behaviors than warnings that do not elicit emotional reactions, and indicate that these effects are well established in the scientific literature.

For example, one comment stated that the scientific literature shows that graphic depictions of the negative health effects of smoking arouse reasonable fears and are associated with greater consideration of health risks, increases in motivations to quit, and ultimately with attempts at cessation. Another comment stated that theoretical models and studies in communications and social psychology suggest that graphic health warnings can be effective because they elicit greater emotional engagement with the information provided and it is that engagement that drives behavior change. Another comment from an academic researcher stated that considerable psychological research suggests that risk is more readily communicated by information that arouses emotional associations with the activity. Emotional reactions can be readily accessed from memory by mere presentation of the stimulus, and appear to be powerful predictors of smoking behavior. Yet another comment stated that growing evidence from controlled experiments and survey research indicates that, compared to text-only warnings, graphic health warnings evoke stronger emotional responses and increase motivations to quit or not start smoking. The comment indicated that these studies are consistent with cognition and neuroscience research demonstrating that relative to linguistic or text information, imagery-based information can be processed more rapidly, evoke stronger emotional responses, induce greater cognitive processing and attitude change and can be recalled more easily.

However, other comments stated that reliance on emotional measures for assessing graphic health warnings is inappropriate. A joint comment from tobacco product manufacturers stated that the study measured only the effect of eliciting strong emotional and cognitive reactions, which confirms that the warnings were intended not to inform consumers with purely factual and uncontroversial information, but rather to shock consumers into adopting the Government's preferred course of conduct. Another tobacco product manufacturer commented that, to the extent FDA selected images based on emotional or cognitive reactions and not

on ability to inform consumers about the health risks of smoking, the regulations would not pass constitutional muster. A comment from a public policy organization commented that emotional and cognitive responses are irrelevant measures of effectiveness if there is no behavior response.

(Response) On the basis of our review of the relevant scientific literature and the feedback received in the docket, we conclude that our inclusion of emotional reaction measures to evaluate the relative effects of the 36 proposed required warnings was appropriate and is consistent with well-established principles in the scientific literature. As discussed in the study report that was placed in the docket (Ref. 49) and in other comments summarized in previously in this document, eliciting strong emotional and cognitive reactions to graphic warnings enhances recall and information processing, which helps to ensure that the warning is better processed, understood, and remembered. Thus, these responses can enhance the effective communication of the health warning message. These responses in turn influence short-term outcomes, such as later recall of the message and changes in knowledge, attitudes, and beliefs related to the dangers of tobacco use and exposure to secondhand smoke. As attitudes and beliefs change, they eventually lead to changes in intentions to quit or to start smoking and then later can lead to lower likelihood of smoking initiation and greater likelihood of successful cessation.

We disagree that use of emotional reaction measurements demonstrates the Agency's intent to advocate a preferred position or course of conduct. Each of the nine graphic warnings required by the final regulations communicates negative health consequences of smoking that are well-established in the scientific literature. Consistent with the Tobacco Control Act, the purpose of these required warnings is to communicate effectively and graphically the very real, scientifically established adverse health consequences of smoking. The overall body of scientific evidence indicates that health warnings that evoke strong emotional responses enhance an individual's ability to process the warning information, leading to increased knowledge and thoughts about the harms of cigarettes and the extent to which the individual could personally experience a smoking-related disease. Increased knowledge and thoughts about the negative consequences of smoking, in turn, are reasonably likely to result in more informed and healthier behaviors, such as trying to quit smoking or deciding not to start.

(Comment 27) We also received two comments concerning the cognitive measure used in the study. A comment filed by tobacco product manufacturers observed that ''looks cool'' was one of the measured cognitive reactions. The comment stated that the study analysis omits responses on whether the warnings ''looked cool,'' and contended that if a substantial number of participants viewed a warning as ''looks cool,'' the warning would be unlikely to have the intended effect. The comment concluded that the ratings for the ''looks cool'' measure do not appear to have been neutral; the comment stated that regression results for the ''looks cool'' measure indicates that this measure elicited one of the strongest estimated effects of the study and the results go in the opposite direction of effectively communicating health risk information.

(Response) We disagree that data concerning the ''looks cool'' outcome was omitted or that the results for this outcome go in the opposite direction of the intended effect of communicating the negative health consequences of smoking. Although the ''looks cool'' outcome was not included in the reported composite cognitive measure, the study report (Ref. 49) includes the results for this measure in its appendices. The measure was reverse coded, so that a higher value corresponded with the intended directionality for other measures. Thus, a high value for ''looks cool'' corresponds to a response of ''strongly disagree'' from the respondent. The data presented in the appendices demonstrate that for each of the nine selected required warnings, significantly more participants disagreed that the warning ''looked cool'' than participants who viewed the text-only control warning. Eight of the nine required warnings elicited significantly higher ratings than the text-only control warning across all target audiences. Ratings for the ninth required warning, which includes the textual statement ''WARNING: Quitting smoking now greatly reduces serious risks to your health,'' show that significantly more adults disagreed that the selected required warning ''looked cool.'' Responses for young adults and youth were in the appropriate direction, but the responses were not significantly different from the text-only control warning.

(Comment 28) We also received a comment concerning the believability measure. This comment raised a concern that some of the 36 proposed required warnings may be perceived as unrealistic because they did not vividly portray immediate health risks, which could lead some smokers to discount the warning. The comment recognized that a believability measure was included in the study as part of the cognitive reaction scale, but stated that specific results for believability were not reported, and recommended that FDA examine the mean scores of the specific believability items in conjunction with other important measures included in the study.

(Response) We agree with the comment that believability is a helpful measure for assessing the relative effectiveness of warning images. All of the selected images scored significantly higher than the controls on the cognition measures, which included ratings on how meaningful the warning was, whether it was informative, and whether it was believable. While the results do not include mean scores for believability and other individual measures, the appendices include the parameter estimates from regression analyses on these individual measures. The results show that, in most cases, the images selected for the nine required warnings scored significantly better than the control with respect to believability.

(Comment 29) One comment stated that the statement recall measure is less important and less relevant to decisions about smoking than negative affective reactions because the warning statements are now believed by smokers and nonsmokers.

(Response) Statement recall was appropriately included as part of the assessment of the relative effectiveness of the 36 proposed required warnings. As discussed in section II.C of this document, while both smokers and nonsmokers have some understanding about some of the risks of smoking, there are significant gaps in their knowledge, including about the magnitude and severity of the risks of smoking. We also note that, as explained in section III.B.2 of this document, although we carefully examined the research results on all the study measures for the 36 proposed required warnings, including recall, the responses on the salience measures served as a more important basis than recall for distinguishing among the 36 proposed required warnings.

(Comment 30) A joint comment submitted by tobacco product manufacturers asserted that the study fails to demonstrate that the published graphic warnings will have any discernible effects on smoking risk beliefs.

(Response) We disagree with this comment. Four of the nine selected required warnings did show a significant impact on beliefs about the health risks of smoking relative to the text-only control among at least one study population. In addition, there is substantial evidence in the scientific literature showing that graphic health warnings effectively increase consumer understanding of the health risks of smoking. In the preamble to the proposed rule (75 FR 69524 at 69531 through 69533), we presented substantial research showing that graphic health warnings significantly increase consumer thoughts about and understanding of the health risks of smoking after they were introduced in other countries. In addition, as discussed previously in this document, considerable scientific evidence shows that health warnings that elicit strong emotional and cognitive reactions are better processed and more effectively communicate information about the negative health consequences of smoking. Each of the nine required warnings elicited strong effects on the emotional and cognitive reaction scales, which indicates that these warning will effectively communication information about the negative health consequences of smoking.

Based on the results of our research study and the existing scientific literature, we conclude that graphic health warnings, including the nine selected required warnings, are likely to increase consumer knowledge and understanding of the health risks of smoking.

(Comment 31) A comment submitted by tobacco product manufacturers criticized the study's use of intentions to measure behavioral change and stated that FDA should have presented data showing actual effects on behavior.

(Response) We disagree that intentions are an inappropriate variable for assessing potential behavioral changes. While measures of intended behavioral outcomes do not perfectly predict a future behavior outcome, it is a necessary precursor. The scientific literature indicates that one's intentions to quit smoking must be increased before one makes the actual quit attempt. Thus, we conclude that it was appropriate in our research study to assess quit intentions as a proxy for behavior change. In accordance with Executive Order 13563, after the rule is in effect we will be undertaking analysis to better understand the behavioral effects of the warnings.

(Comment 32) Several comments raised concerns that the lack of strong statistically significant results concerning intentions in FDA's research study is an indication that the required warnings will not be effective. For example, a comment submitted by tobacco product manufacturers stated that the results of FDA's research study show that graphic health warnings will not result in a statistically significant reduction in youth initiation or overall prevalence of smoking, and thus, confirms that the warnings will not be effective.

(Response) We disagree that our study results indicate that the required warnings will not be effective. It is important to recognize that FDA's research study was not designed or intended to produce evidence demonstrating actual effects on behavior. Rather, the study was designed to provide data concerning the relative effects of the graphic health warnings in order to provide a more objective and scientific basis for our selection of the set of nine required warnings in the final regulation. There is considerable evidence in the scientific literature demonstrating that graphic health warnings effectively increase awareness of the health risks of smoking, which is the principal purpose of the warnings, and that this awareness in turn can influence smoking intentions and behaviors. We included significant research to substantiate this conclusion in the preamble to the proposed rule (*see* 75 FR 69524 at 69531 through 69533). For example, as discussed in the proposed rule, a 2007 report from an expert IOM panel that evaluated the existing scientific evidence on health warnings concludes that the available scientific evidence indicates that larger, graphic health warnings would promote greater public understanding of the health risks of using tobacco and would help to reduce consumption (Ref. 3).

FDA's research study cannot be viewed in isolation from the overall body of scientific evidence evaluating the efficacy of graphic health warnings. While the research study itself did not provide evidence of strong effects on intentions (which, as noted in section III.B.2 of this document, is not surprising given the single-exposure design of the study), the overall body of scientific literature does provide sufficient evidence that the required warnings, by increasing public understanding of and thoughts about the health risks of smoking, will be effective in encouraging smoking cessation and discouraging smoking initiation.

A number of comments provide additional support for our conclusion. For example, a comment from a researcher conducting an international longitudinal study on graphic health warnings states that studies show that graphic depictions of smoking's adverse effects on the body are associated with greater consideration of health risks, increases in motivations to quit smoking, and ultimately, attempts at cessation. A comment by a researcher with expertise in risk perceptions and decisionmaking concludes that emotional associations to smoking appear to be powerful predictors of smoking behavior and may well be causally implicated in efforts to either stop or start smoking.

(Comment 33) A comment from tobacco product manufacturers stated that the responses to the ''smoking urges'' questions included in the study would provide a better measure for assessing whether the proposed required warnings affected smoking behavior and, referring to the responses regarding these questions, the comment asserts that, on balance, seeing the proposed required warnings increased the desire to have a cigarette rather than decreased it.

(Response) We disagree that our research study shows that, on balance, seeing the proposed required warnings increased the desire to have a cigarette. The ''smoking urges'' measures were reverse coded, so that a higher value corresponded with the intended directionality for other measures in the study. Thus, a high value corresponds to a response of ''strongly disagree'' from the respondent. The data presented in the study report appendices (Ref. 49, study report) show that, for three of the nine selected required warnings, significantly more participants in at least one target group disagreed with the statement that they wanted a cigarette than participants exposed to the text-only control warning. For one of the selected required warnings, significantly more adult participants who viewed the warning on a cigarette pack disagreed that they wanted a cigarette, but significantly more adults who viewed the warning in a cigarette advertisement agreed. For one of the selected required warnings, significantly more participants in one target audience agreed that they wanted a cigarette than participants exposed to the text-only control warning. Results for the remaining selected required warnings and sample groups were not significantly different from the text-only control warning.

Thus, on balance, the study does not show that exposure to the final set of nine images increased the desire to smoke a cigarette among study participants. As discussed in the previous response, the overall body of

scientific literature provides ample evidence that the required warnings, by increasing public understanding of and thoughts about the health risks of smoking, are likely to encourage smoking cessation and discourage smoking initiation. Data from our research study regarding ''smoking urges'' provide no basis for calling into question that evidence.

d. *Study limitations and issues regarding methodology.* A number of comments discussed a wide variety of issues concerning limitations of FDA's research study and raised various issues concerning the study methodology.

(Comment 34) Several comments, including comments from health institutions, nonprofit organizations, and academics, raised concerns that the demographics of FDA's research study did not include adequate sample sizes for minority populations and persons of lower income or lower education status. These comments noted that the findings of the study therefore may not be relevant to populations with high smoking prevalence and to those consumers who might be most impacted by graphic health warnings. Some of the comments recommended further testing in these populations.

(Response) We recognize the importance of reaching populations with high smoking prevalence, including various racial/ethnic groups and persons of lower income or lower education status. The study report provides analyses of the relative effects of the images within various sub-groups, separating samples by gender, race, and education. The analyses, for the most part, confirm that the relative effects of the images are consistent across groups. As such, we have determined that the required warnings will help to effectively convey the negative health consequences of smoking to a wide range of audiences, including different racial and ethnic populations and different socioeconomic groups.

(Comment 35) A comment from tobacco product manufacturers criticized the study methodology because it did not include a nationally representative sample of participants and claimed that this failure biased the study results. The comment stated that the study report (Ref. 49, study report) fails to disclose basic sampling information and provides no indication that those conducting the study adjusted for the effect of choosing participants by soliciting volunteers. The comment concluded that this failure was significant because the participants in the study may not reflect the population of interest and may bias the statistical estimates.

(Response) We disagree that the study results are invalid due to the demographic composition of the sample. The research study was not intended to be a survey of the national population, but rather a study using random assignment to study conditions. The study included individuals from certain target groups, particularly current smokers and youth who may be susceptible to initiation of smoking. Statistical methods were used to assess the relative impact of each of the proposed required warnings on various outcomes, rather than to assess the absolute impact one would expect to observe in the U.S. population as a whole.

(Comment 36) One comment raised a concern that lack of adequate pretesting of the proposed required warnings evaluated in FDA's research study could compromise the overall effectiveness of the pool of images tested. The comment stated that it would have been more helpful to conduct pilot testing with a very large group of images (at least 20 per textual warning statement) to ensure testing and selection of the most effective graphic warnings.

(Response) We agree that more extensive pretesting may have been useful. However, we disagree with the suggestion that the overall effectiveness of the required warnings could be compromised by the inability to conduct additional pretesting prior to the research study. The results of the research study as well as research submitted by others during this rulemaking proceeding indicate that the overall efficacy of the pool of proposed required warnings is quite strong. Based on those data, as well as the overall scientific literature, we conclude that the required warnings will effectively communicate the negative health consequences of smoking to smokers and nonsmokers.

(Comment 37) A comment submitted by tobacco product manufacturers asserted that selection bias is a serious methodological flaw of the study. The comment stated that participants were recruited from an Internet panel and offered the opportunity to participate in the research study, creating a selection bias that was compounded by the fact that the invitation to participate stated that the study was funded by FDA. The comment noted that there is no indication that the study corrected for the selection bias and opines that one would not expect the selection bias to be neutral given the identification of FDA as the sponsor of the study.

(Response) We disagree that selection bias is a serious methodological flaw of the study. Although we acknowledge the potential for selection bias, we disagree that this potential bias was likely to significantly affect the results of the study. Even if participants who approve (or disapprove) of FDA were more likely to participate in the study, one would expect that bias would affect all of the experimental conditions, including the text-only control warnings. A bias of this sort would affect the absolute effects of the warnings in general, but not the pattern of relative effectiveness of individual warnings. As a result, selection bias does not invalidate the results of the study, which provides insight on the relative effectiveness of the various warnings under consideration.

(Comment 38) A comment from tobacco product manufacturers stated that FDA's research study is seriously flawed because 32 percent of the participants dropped out of the study before completing the questionnaire. The comment stated that quitting the survey was not likely to be a random event and may have been a result of smokers who are not receptive to graphic health warnings dropping out. If so, the comment suggested that this would have significantly overstated the results of the study.

(Response) We disagree that the drop-out rate observed in the study undermines the validity of the results of the study. Table 3–1 from the methodology report displays the total number of individuals entering the study. However, these values represent the total number of individuals who entered the study's ''landing page,'' which is the site to which invitees link from the e-mail invitation. The invitation from e-Rewards, as well as the landing page, refers to the study as a ''Study about Consumer Products.'' There were no references to FDA, smoking, or tobacco in either the invitation or the landing page. Though it is true that a number of invitees chose not to continue after seeing the invitation or the landing page, their decision not to participate cannot be attributed to a bias for or against FDA or the implementation of graphic health warnings on cigarettes.

In addition, the number of individuals identified as ''Quits'' in table 3–1 of the methodology report includes individuals who quit after viewing the landing page and those who quit after having been informed of FDA's involvement and that the survey concerned smoking or tobacco. Of those individuals identified as ''Quits'', only a very small number were in the latter group (*i.e.,* quit after being informed of FDA's involvement and that the survey concerned smoking or tobacco). For

example, of the 13,673 respondents who entered the adult pack survey (the point in time when they viewed the study's landing page), 2,179 chose at some point to discontinue. Of these, only 148 individuals, or about 1.1 percent of those entering the study, chose to discontinue the survey after being informed of FDA's involvement and that the survey concerned smoking or tobacco. A similar pattern exists for all of the study samples: In the adult pack follow-up sample 23 individuals, or 0.6 percent, chose to discontinue after being informed; in the adult ad study sample 193 individuals, or 2.1 percent, chose to discontinue after being informed; in the adult ad follow-up sample 26 individuals, or 0.7 percent, chose to discontinue after being informed; in the young adult study sample 152 individuals, or 1.3 percent, chose to discontinue after being informed; in the young adult follow-up sample 11 individuals, or 0.3 percent, chose to discontinue after being informed; in the youth study sample 104 individuals, or 0.3 percent, chose to discontinue after being informed; and in the youth follow-up sample 13 individuals, or 0.5 percent, chose to discontinue after being informed. The drop-out rate, as calculated here, varies across the study samples but never exceeds 2.1 percent. Therefore, we do not agree that the drop-out rate invalidates the results of the study.

(Comment 39) A comment from tobacco product manufacturers stated that the youth component of FDA's research study is subject to a response bias. The comment stated that the study failed to address the risk that the youth participants might alter their responses due to a concern that their parents might see the results.

(Response) We disagree that the youth sample is likely subject to a response bias. Youth participants were told at the outset of the study that their responses would be kept confidential. Once the study was complete, other household members could not retrieve those responses. Moreover, if youth participants were concerned about parental awareness of their participation, it would likely have resulted in a decision not to participate rather than a decision to alter their responses.

(Comment 40) A comment from tobacco product manufacturers raised a concern that the youth sample is subject to a selection bias because participants were derived from families whose parents also participated in the study.

(Response) We disagree. As discussed in section 2.2.3 of the methodology report (included in the docket as part of the study report (Ref. 49, study report)), most of the youth were sampled from a separate youth panel, which was independent of the adult panel. Some of the youth were sampled from the households of the adult panel. However, those in the latter group were sampled independently and randomly from the adults that participated in the study. Although possible, it is unlikely that both a parent and child from a single household received an invitation for the study and completed the study.

(Comment 41) A comment from tobacco product manufacturers objects to the manner in which the study assessed emotional and cognitive reactions. The comment states that the study weighted the responses to multiple questions, but fails to disclose the weights used and the justification for those weights, and states that without information on the weighting system, one cannot assess these measures for bias.

(Response) We disagree with this comment. Section 4.2 of the methodology report for our research study (included in the docket as part of the study report (Ref. 49, study report)) indicates that a factor analysis was used to determine the appropriate items to include within each scale. A weighting scheme was not used. Rather, items were combined using a simple summative scale. Use of a simple summative scale is a widely-used method of analyzing these data.

(Comment 42) A comment from tobacco product manufacturers states that the study used an inappropriate methodology by measuring risk awareness and smoking intentions on a scale. The comment states that evaluating these measures on a scale is inappropriate for testing awareness of a fact and also resulted in the authors making subjective and undisclosed decisions about how to weight those values.

(Response) We disagree. It is appropriate to measure the impact of a warning on the strength of an individual's awareness, beliefs, and intentions. To do this, one must use a scaled response, rather than a dichotomous response, to each question. In the research study, items were not weighted within each scale. Rather, they were combined using a simple summation of ratings. This is a widely-used methodology for this type of study.

(Comment 43) A report attached to the comment from tobacco product manufacturers criticizes FDA's research study for failing to assess baseline knowledge among participants to determine whether the proposed required warnings increased awareness of the health effects of smoking.

(Response) The lack of an assessment of baseline knowledge does not make the study results less reliable or invalid. In a study such as FDA's research study, responses to the control conditions serve as proxies for baseline knowledge, awareness, beliefs, and intentions. Comparing the treatment responses to those of the control allow for an assessment of the potential impact the treatment has on baseline measures.

C. Comments to the Docket

FDA received hundreds of comments on the 36 proposed required warnings; the comments relating to each proposed required warning are discussed in sections III.D and III.E of this document. Some comments discussed the 36 proposed required warnings generally or discussed different styles or themes used in the set of proposed required warnings. These comments are summarized and responded to in this section.

As explained in section III.A of this document, we considered the comments submitted to the docket as we determined which color graphic images to require to accompany the nine textual warning statements in the final rule. We did not simply count the number of comments received supporting or opposing the use of a particular image as a way to measure the relative effectiveness of our proposed images or of images recommended by comments, but rather evaluated the substantive input contained in the comments to help inform our decisions in selecting or not selecting a particular image and to obtain other relevant information related to research on the images. Many of the comments contained information about the submitter's personal opinions, beliefs, and attitudes related to various images. While this information is helpful in understanding how people might interpret various images and in raising issues for further exploration, this type of qualitative information is not as useful as quantitative assessments of the relative effectiveness of the 36 proposed required warnings at conveying information about the negative health consequences of smoking, such as the assessment provided in FDA's research study.

Furthermore, as described in more detail in the comment summaries and responses in sections III.D and III.E of this document, some of the information contained in comments that criticized or opposed the use of various proposed images suggested that the images evoked negative emotional reactions in the viewer. The research literature,

however, suggests that warnings that evoke these reactions can increase the likelihood smokers will reduce their smoking, make an attempt to quit, or quit altogether (Ref. 44).

1. Comments Submitting Research on FDA's Proposed Required Warnings

We received several comments, including comments from academics, a nonprofit organization, and a prevention specialist, that described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed required warnings on various outcomes. We address that research and our responses to these comments in the comment summaries and responses in this section. The information contained in these comments about particular proposed required warnings is also discussed as applicable in sections III.D and III.E of this document.

As is discussed in the summaries in this section, the nine required warnings we have selected for use on cigarette packages and in cigarette advertisements generally performed well in the studies discussed in these comments. These comments indicate that the findings from our own research study are robust, as they have generally been confirmed under the various different study designs utilized in the research discussed in these comments.

However, in contrast to our own research study, we did not have access to the raw data or to all the statistical analyses for the studies discussed in these comments. In addition, the design of some of these studies did not allow for an assessment of the relative effectiveness of FDA's 36 proposed required warnings. This limited the utility of the information provided in the submissions.

Thus, while we carefully considered the information provided in these submissions, the results of our own study were more helpful in making research-based selection choices.

(Comment 44) One study was submitted by a group from a medical institution and by a collaborating academic who has conducted research on graphic health warnings. Participants were recruited from an Internet panel of adults, young adults, and youth. The report for the study states that it was intended to assess the potential effectiveness of FDA's 36 proposed required warnings. Among other things, participants were asked to provide certain demographic information as well as information concerning their smoking status and attitudes and beliefs about smoking. In addition, the study tested nine ''sets'' of warnings, one for each of the textual warning statements required by the Tobacco Control Act. Each set included each of the proposed required warnings published with the proposed rule for use with the specific textual warning statement as well as at least one alternative warning. Each participant was randomly assigned to view and rate two sets of health warnings.

Warnings within each set were first rated individually on a scale of 1 to 10 and then participants were asked to rank order the entire set for perceived effectiveness for discouraging smoking. The comment presented the rating and ranking scores for the health warnings. The comment also presented preliminary statistical analyses for the overall ranking scores; statistical data were not presented for individual ratings for the individual measures assessed. The comment concludes that preliminary results from the study show that warnings that were more explicit about the health risks of smoking were rated as being more effective among both adults and youth. The academic who conducted the study similarly concluded that health warnings that were more explicit and that elicited greater emotional reactions were rated as being most effective, and the researcher recommended that FDA select certain graphic warnings that received high rating and ranking scores in the study (including required warnings proposed by FDA as well as graphic warnings that have been used in other countries).

(Response) The results of this study are generally consistent with the results of the scientific literature and the study sponsored by FDA. This study shows that the existing cigarette warnings are not salient among either adults or youth. Among other responses, 50.3 percent of adults responded that they never or rarely noticed the health warnings on cigarette packs, while 23.7 percent stated that they often or very often noticed the warnings. Among youth, 63.3 percent responded that they never or rarely noticed the health warnings on cigarette packs, while 12.9 percent stated that they often or very often noticed the warning. The graphic warnings selected for inclusion in the final regulation generally performed relatively well in both this study and in FDA's research study. It is difficult to assess the results of this study more specifically without additional information concerning the study protocol, methods, and statistical analyses.

(Comment 45) A study was submitted by a researcher with expertise in risk perceptions and decisionmaking. Participants were young adult college students, including smokers, nonsmokers, and ''vulnerable'' nonsmokers. The study assessed emotional reactions, risk perceptions, and smoking aversion. Participants were randomized into four conditions, with each viewing 18 graphic warnings. Two conditions viewed graphic warnings being used in other countries, one condition viewed 18 graphic warnings published with the proposed rule, and the fourth condition viewed the proposed FDA graphic warnings plus three graphic warnings from other jurisdictions. According to the comment, warnings ''that were perceived as more graphic, more intense, less good, and more fearful produced more thoughts about not wanting to smoke.'' The comment concludes that, compared to the viewed warnings being used in other countries, the FDA proposed required warnings did not maximize thoughts of health risk perceptions or smoking aversion, although the differences between the warnings from other jurisdictions and FDA's proposed required warnings were marginal.

(Response) The nine required warnings that we have selected performed relatively well in this study. Many performed as well as the warnings from other jurisdictions and some performed better. It is difficult to assess the results of this study more specifically, however, without additional information concerning the study protocol, methods, and statistical analyses.

(Comment 46) A study was submitted by a group of behavioral scientists whose research focuses on cognitive, emotional, and imagery processes that influence how people respond to messages about health risks. Their experimental study evaluated the 36 proposed required warnings published with the proposed rule. Participants were young adults ages 18 to 25, and included smokers and nonsmokers. Each participant viewed 18 of the 36 proposed required warnings and was asked to rate each on the following measures: Perceived comprehension, worry about the health risks of smoking, and the extent to which the warning discouraged the participant from wanting to smoke a cigarette. The comment states that the study provides strong support that most of the graphic warnings proposed by FDA are perceived by young adult smokers as easy to understand, as enhancing worry about the health risks of smoking, and as discouraging young adult smokers from wanting to smoke. The comment states that the results of the study are consistent with the growing body of

evidence showing that, compared to text-only warnings, graphic warnings can evoke stronger emotional responses and reduce motivations to smoke.

(Response) The nine required warnings that we have selected performed relatively well in this study. It is difficult to assess the results of this study more specifically without additional information concerning the study protocol, methods, and statistical analyses.

(Comment 47) A study was submitted by two researchers at a university-based public policy center. The comment states that the study, of young adult and adult smokers, was conducted to assess limitations of the FDA study and to identify ways to increase the impact of the warnings. The study used the same online survey firm as that used in the FDA study, although respondents who participated in the FDA study were not eligible to participate in this study. The study was limited to four of the nine warning statements required by the Tobacco Control Act. The graphic warnings assessed for each of these four statements included some of the proposed FDA warnings, these same proposed warnings with additional text or color added, and some graphic warnings used in Canada. Graphic warnings were compared against a text-only control warning that appeared on the side of a cigarette pack. The study used two indices to assess efficacy. The first assessment was perceived effectiveness in discouraging someone from smoking. For the second assessment, participants were asked to imagine themselves smoking a cigarette and then to report how good or bad they would feel smoking a cigarette. The comment states that in three of the four warning messages required by the Tobacco Control Act, a single exposure to a large graphic warning was more effective in creating immediate negative emotional associations with the act of smoking than exposure to the text-only warning. The comment states that the study did not show that the single exposure affected immediate plans to quit smoking; the authors of the comment note that a brief test following a single exposure is unlikely to detect this effect, and that they would expect quit intentions to increase through repeated exposures to the warnings.

(Response) The proposed required warnings published by FDA and included in this study performed relatively well in this study. It is difficult to assess the results of this study more specifically without additional information concerning the study and the statistical analyses.

(Comment 48) An organization of high school students submitted the results of a study they conducted to assess the efficacy of the 36 proposed required warnings published with the proposed rule. Organization members recruited participants from their high schools and communities. Each participant viewed 18 of the proposed required warnings and was asked to rate each warning for perceived effectiveness in stopping someone from smoking. Findings were reported as arithmetic means and modes. The comment concludes that study respondents generally believed that the most effective images were the more graphic images.

(Response) We note that the nine required warnings we selected generally rated highly in this study.

(Comment 49) One comment contained the results of a study conducted by two individuals among college students at a U.S. university. In this study, 63 college students, apparently including both smokers and nonsmokers, were shown the 36 proposed required warnings and asked to rate them on a scale of 1 to 7 on their perceived effectiveness in helping smokers' intent to quit. According to the comment, certain demographic information also was obtained from participants. The comment identifies the five proposed required warnings that were ranked as being the most effective warnings and the five proposed required warnings that were ranked as being the least effective. According to the comment, demographic factors did not affect the rating scores. The only factor identified as having an impact on rating was smoking status, with participants who had a history of smoking more likely to rate the graphic warnings as being effective than subjects who did not have any history of smoking.

In another comment, submitted by a self-identified prevention specialist from a U.S. public school district, 1,339 high school students viewed the 36 proposed required warnings and were asked ''which image would change your mind about smoking.'' The comment identified the ''top three'' proposed required warnings.

(Response) We note that the proposed required warnings chosen as ''most effective'' include some of the nine required warnings we selected. Neither of these comments included sufficient information or data with which to further assess the results or conclusions.

2. Other Comments

FDA also received a number of other comments that discussed the proposed required warnings generally or highlighted issues that applied to some or all of the proposed required warnings. These comments are summarized and responded to in the following paragraphs.

(Comment 50) Many comments stated that graphic health warnings that elicit strong emotional responses are most effective in communicating the negative health consequences of smoking and in encouraging smoking cessation and discouraging smoking initiation. Most of these comments recommended that FDA select the warnings that evoke the strongest emotional responses. Some of these comments cited graphic warnings used in other countries or international research showing that images that trigger emotional responses promote greater awareness and better recollection of the health risks of smoking. Some of these comments also stated that warnings that trigger these responses retain their effectiveness longer. Some of these comments recommended that FDA select graphic warnings that portray graphically disturbing images or images that evoke fear or disgust.

(Response) We agree that eliciting strong emotional responses helps communicate health information. The overall body of scientific literature indicates that health warnings that evoke strong emotional reactions enhance an individual's ability to process the warning information. This leads to increased knowledge and thoughts about the health risks of smoking and the extent to which an individual could personally experience a smoking-related disease, which can in turn motivate positive behaviors. For example, the literature suggests that risk information is most readily communicated by messages that arouse emotional reactions (*see* Ref. 45), and that smokers who report greater negative emotional reactions in response to cigarette warnings are significantly more likely to have read and thought about the warnings and more likely to reduce the amount they smoke and to quit or make an attempt to quit (Ref. 44). The research literature also suggests that warnings that generate an immediate emotional response from viewers confer negative affect to smoking cues and undermine the appeal and attractiveness of smoking (Ref. 45 and Ref. 40 at pp. 37–38). In FDA's study, eight of the nine selected required warnings elicited strong emotional reactions across all target audiences. As is further discussed in section III.D of this document, the ninth selected required warning, which, unlike the other eight required warnings, contains a warning statement that is framed in a positive manner, also

showed significant effects on the emotional reaction scale in one study population. Given the manner in which this ninth warning is framed, it is not expected to arouse the same level of response on the emotional reaction scale used in FDA's research study as the other eight warning messages (*see* section III.D of this document).

Some of the required warnings we selected include images that may be more emotionally disturbing to certain individuals than others. As we discussed in the preamble to the proposed rule, the use of health warnings with disturbing tonal qualities appears to be effective (75 FR 69524 at 69534). But research also indicates that other types of graphic images, including some that individuals do not find frightening or disturbing, can also be effective in communicating the health risks of smoking (*Id.*). The set of nine graphic warnings we selected includes a balanced set of images in order to reach the broadest target audience of smokers and potential smokers.

(Comment 51) Some comments raised concerns about the quality of the proposed required warnings published by FDA. Some believed that the proposed required warnings were weaker than those used in other countries, and thus, would be less impactful than those in use in other countries. A few comments said the images were overdone and insulting, and a few indicated that the submitters believed that the visuals were poorly crafted.

(Response) We disagree with these comments. We have chosen a balanced set of images for use with the required warnings, and these warnings are generally consistent with the graphic health warnings used in other countries. The results from our research study and the overall body of scientific literature on graphic warnings provide a strong basis for concluding that the nine selected required warnings will effectively communicate the negative health risks of smoking to smokers and potential smokers.

(Comment 52) Some comments raised concerns that the proposed required warnings were too explicit and too visually disturbing. Some of these comments raised concerns that the images were too disturbing for children to see, and others indicated that nonsmokers should not have to be subjected to ''gross'' images when they go into retail establishments. Two comments raised concerns that images that showed humans in distress or human remains were disrespectful and degrading. One comment stated that the proposed warnings crossed the line and were an effort to manipulate people to stop smoking or not to start.

(Response) We disagree. The set of nine required warnings we selected include a balanced set of images. Some individuals may find certain images more visually disturbing than others. The images are not intended to shock or disturb, but rather to effectively educate and inform smokers and potential smokers about the serious health consequences of smoking. Each of the nine graphic warnings communicates negative health consequences of smoking that are well-documented in the scientific literature. By appropriately conveying the serious health consequences in a truthful, forthright manner, the images contain information that may disturb some viewers because the severe, life-threatening and sometimes disfiguring health effects of smoking *are* disturbing. The overall body of scientific evidence indicates that larger, graphic health warnings will effectively communicate these risks. We do not agree that these warnings are disrespectful or degrading.

(Comment 53) A number of comments advocated for the selection of a set of images that could communicate with the diverse U.S. population, and emphasized the importance of human diversity in the images, in part to help ensure the images reach people of low socioeconomic status that are more likely to be smokers and/or to have lower literacy. The comments stated that graphic health warnings are an especially important communication tool for these population groups. A few comments also raised concerns that not enough of the 36 proposed required warnings depicted younger people, and indicated this could reduce their impact among youth.

(Response) We agree that it is important to select a set of images that can communicate with the diverse U.S. population. As discussed in section III.A of this document, we considered the need for diversity when making image selections, and the images selected include a diversity of human images (*e.g.,* race, gender, age), as well as a diversity of styles (*e.g.,* photographic versus illustrative) and themes. This is consistent with the evidence base for graphic health warnings from countries that have already implemented such warnings (*see* Ref. 40 at p. 46 and Ref. 11).

(Comment 54) A number of comments raised concerns that some of the proposed graphic warnings included graphic illustration or ''cartoon-style'' images. Some of these comments stated that these warnings might trivialize the serious health risks of smoking or diminish the importance of the warnings, with some asserting that this style is contradictory to the serious messages being conveyed. One comment believed that these warnings would soften the message, while another believed the graphic illustration warnings were ''harsh.'' Some comments stated that these warnings would negatively affect the believability of the warnings and would not be taken seriously by youth. One comment expressed concern that the graphic illustration style images might resonate with youth, but would not be effective with young adults or adults. It was also noted in the comments that the images presented in this style may inadvertently suggest approval of tobacco use to low-literacy populations that do not comprehend the accompanying textual statement, and that these images could allow smokers to deny the health consequences that are presented. Another comment stated that the research suggests ''cartoon-style'' images and overly conceptual images are easily dismissed by smokers.

(Response) We disagree with the contention that the use of graphic illustration style images is categorically inappropriate. One of the required warnings we selected is presented in this style. As discussed in section III.B of this document, our research study shows that the selected required warnings, including the required warning that includes a graphic illustration style image, showed strong effects in terms of emotional reaction scale, cognitive reaction scale (including believability), and the ''difficult to look at'' measure. Given these results, we concluded that the graphic illustration style can be an effective style for communicating the negative health risks of smoking, including to a diverse range of viewers. In addition, it is important to include a variety of different styles in the final set of warnings. As discussed in the preamble to the proposed rule, a varied set of warnings is consistent with the scientific literature, facilitates better targeting of specific groups whose interests may vary, and has been shown to be effective in delaying or counteracting wear out of the warnings (75 FR 69524 at 69534).

(Comment 55) A number of comments advocated that FDA select only required warnings with photographic images. Some of these comments stated that the use of photographic images was important to realistically portray the negative health consequences of smoking and to provide a real-life quality to the warnings. One comment stated that photographic images were needed to ensure that smokers and

potential smokers understood that the depicted health consequence could really happen and to provide a more physical connection. One comment stated that photographic images would be more engaging and remembered than images presented in other styles. One comment stated that warnings with abstract imagery that require individuals to ''connect the dots'' and draw inferences present an unnecessary and counterproductive hurdle for viewers, and are unlikely to have an effect on smokers.

(Response) We agree that graphic warnings with photographic images can effectively communicate the negative health consequences of smoking, and most of the required warnings we selected include photographic images. The existing scientific literature, the experience of other countries, and the results of our research study show that graphic warnings using photographic images can effectively communicate the negative health consequences of smoking. At the same time, we do not agree that photographic images are the only style of imagery capable of effectively communicating these health risks. A balanced set of warnings with a variety of image styles is more likely to effectively reach a broad group of target audiences, and we note that graphic warnings used in many other countries include a mix of imagery, including photographic and other styles.

(Comment 56) Some comments stated that graphic warnings will not be effective in deterring smoking. One comment stated that smokers already know the health risks of smoking and are very brand loyal, so graphic images will not affect their smoking decisions. Another comment stated that youth will not be deterred by pictures and the graphic warnings could instead make smoking more enticing to youth. One comment stated that smokers are addicted to cigarettes and ''flashy'' pictures will not stop them from smoking but instead will only encourage them to cover the pictures. On the other hand, other comments concluded that graphic health warnings are likely to affect smoking decisions. One comment stated that graphic warnings will deter initiation, and another stated that the warnings will lead to a decrease in cigarette sales. One comment stated that graphic warnings will reach people who otherwise would not read text-only warnings.

(Response) As previously discussed, we concluded that large graphic warnings are effective in conveying the health risks of smoking, influencing consumer awareness and knowledge of those risks and having an impact on smoking intentions. We disagree with comments stating that required warnings will not be effective. We have determined that the set of required warnings we have selected will effectively convey the negative health consequences of smoking, which will help discourage nonsmokers, including children and adolescents, from starting to smoke cigarettes, and help encourage current smokers to consider cessation to greatly reduce the serious risks that smoking poses to their health.

(Comment 57) Several comments stated that images that depict realistic suffering caused by tobacco use are more effective in promoting cessation than images that portray death.

(Response) We agree that graphic warnings that depict the realistic suffering caused by tobacco use can be effective at communicating the negative health consequences of smoking, and some of the required warnings we selected include such images. At the same time, we do not agree that such images are the only images capable of effectively communicating the negative health consequences of smoking. A balanced set of warnings with a variety of image themes is most likely to maximize the effectiveness of the selected required warnings among a broad group of target audiences, and notes that graphic warnings used in many other countries include a mix of imagery. As discussed in the preamble to the proposed rule, the existing research indicates that the use of a variety of health warnings broadens the reach of the warnings, and is effective in counteracting overexposure and delaying wear out of the warnings (75 FR 69524 at 69534).

(Comment 58) One comment stated that most of the proposed images are illustrations rather than graphic warnings, in that they are meaningful only to people who are already aware of the information in the accompanying textual warning.

(Response) Consistent with the requirements of section 201 of the Tobacco Control Act, we have developed color graphic images that depict the negative health consequences of smoking to accompany the nine new warning statements provided by Congress in the Tobacco Control Act. The graphic health warnings, referred to as ''required warnings'' in the NPRM and in this final rule, consist of the combination of each textual warning statement and the accompanying color graphic image we selected for use with each statement. The submitter of this comment seems to misunderstand how the images are to be used; they were not developed to serve as stand-alone warning messages, but rather to accompany textual warning statements. Although we disagree with the contention in this comment that the images are only meaningful in conjunction with the information in the accompanying textual warning, the images are required to be presented at all times with this accompanying information.

D. Selected Images

This section discusses the nine color graphic images that we selected for use with the textual warning statements set forth in section 201 of the Tobacco Control Act and the factors that influenced each selection decision, including the results from our research study, the substantive comments received in the docket, the relevant scientific literature, and any other considerations weighed, such as the diversity a particular image contributes to the overall set of required warnings.

The document entitled ''Proposed Required Warning Images'' that was included in the docket for the proposed rule displayed each of the 36 proposed required warnings (consisting of the proposed images and accompanying warning statements) on two consecutive pages, with one display showing the warning statement accompanying the image in black text on a white background and one display showing it in white text on a black background. The images are referred to in this section by the pages on which they appear in the ''Proposed Required Warning Images'' document and by the descriptive names used for each image in the study report (Ref. 49) summarizing the results of our research study.

In this section's discussion of the results from our research study for each selected image, the endpoints that the images showed a statistically significant effect on in one or more of the study populations (adult smokers aged 25 or older, young adult smokers aged 18 to 24, and youth who currently smoke or who are susceptible to smoking aged 13 to 17) are described. This discussion also notes the level of significance of the effects by providing p-values: ($p<0.05$), ($p<0.01$), and ($p<0.001$). The p-value is reflective of the percent chance the finding could have happened by coincidence. For example, for a finding that is significant at 0.1 percent ($p<0.001$), there is less than one chance in a thousand that the finding happened by coincidence. The full description of our research study and the analyses are contained in the study report (Ref. 49, study report) that was placed in the docket for the proposed rule.

The required warnings, consisting of the nine color graphic images we selected and the textual warning statements, are contained in a document titled ''Cigarette Required Warnings,'' as is further discussed in section V of this document.

1. ''WARNING: Cigarettes are Addictive''

We selected the image which appears on pages one and two of the document ''Proposed Required Warning Images,'' referred to as ''hole in throat,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on all salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). The image had the numerically largest effects of the images proposed for use with this warning statement on the emotional reaction scale and the difficult to look at measure in all three study populations, as well as on the cognitive reaction scale in adults. As discussed in section III.B of this document, these salience impacts are important, as the research literature suggests that they are likely to be related to behavior change.

The image also had a significant impact ($p<0.05$) on adult [4] beliefs about the health risks of smoking for smokers, and a significant impact ($p<0.05$) on adult beliefs about the health risks of secondhand smoke exposure for nonsmokers, relative to the text-only control.

However, young adults viewing the image had significantly lower statement recall at one week follow-up than those who viewed the text-only control (55.9 percent versus 74.3 percent), as did adults viewing a hypothetical advertisement containing the proposed required warning (64.1 percent versus 87.7 percent). However, recall of the statement was generally high for the image (ranging from 55.9 percent to 86.3 percent), even where it was significantly lower than for the text-only control, and we conclude that repetitive viewing of the required warning is likely to increase recall. As explained in section III.C of this document, we gave greater weight to outcomes on the salience measures than to outcomes on the recall measures.

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 59) FDA received a large number of comments supporting the use of the image ''hole in throat,'' including comments from individuals (including former smokers), public health advocacy groups, academics, State and local public health agencies, and health care professionals. Many comments stated that this image is the best image for use with this warning statement. Some comments indicated that the image was appropriately compelling and effectively communicates the risks of smoking. Other comments stated that the image will be an effective deterrent to smoking by making a smoker think twice before buying cigarettes and/or by making children think twice before starting to smoke. Several comments also indicated that the image concretely conveys the health harms of smoking.

(Response) We selected this image for use with this warning statement.

(Comment 60) One comment supported use of this image in part because of the diversity reflected in the image, and noted that it could be a Latino smoker or a man of color, which could make it more relevant than other proposed images with low socioeconomic status smokers. Another comment noted that the image targets a critical demographic group by portraying an image of a man.

(Response) We agree that it is beneficial to have a diverse set of images that communicates with a wide range of audiences, including population subgroups with higher smoking prevalence rates. In light of this, we selected a set of nine required warnings (including the image ''hole in throat,'' which portrays a man of color) that includes a variety of human images that are broadly representative of the overall population.

(Comment 61) As mentioned in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. The submitter concluded that this image was the most effective of the images proposed for use with this warning statement. Additionally, this image was one of two images deemed effective in another submitter's survey of comparative effectiveness of the 36 proposed required warnings at stopping someone from smoking, and it received the highest overall rating of the images examined for use with this statement in another submitter's study of the potential effectiveness of the images.

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 62) FDA also received some comments that opposed the use of the image ''hole in throat.'' One comment noted that the image was ''too gross to be effective,'' while another comment stated that it ''offend[s] against human dignity.'' In addition, one comment stated that the image would only have a one-time shock value, and another comment indicated that the image was too vague in nature.

(Response) We disagree with these comments. The image effectively and concretely communicates the negative health consequences of smoking. The image clearly portrays the addictive nature of cigarettes, depicting a man who is still smoking despite prior evidence (a stoma in his neck) of surgery for cancer. As discussed, this image had a highly significant effect ($p<0.001$) on all salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). The research literature indicates that images that evoke emotional reactions can promote greater awareness and better recollection of the health risks of smoking, and can increase the likelihood smokers will reduce their smoking, make an attempt to quit, or quit altogether (Ref. 20, 44, and 45).

Furthermore, contrary to the assertion that the image will only have a one-time shock value, the research literature suggests that more vivid warnings are more likely to retain their salience over time (Ref. 3 at p. C–4 and Ref. 41).

2. ''WARNING: Tobacco Smoke Can Harm Your Children''

We selected the image which appears on pages 9 and 10 of the document ''Proposed Required Warning Images,'' referred to as ''smoke approaching baby,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on all the salience measures (emotional reaction scale, cognitive reaction scale, and

[4] Throughout this section, the results on individual study measures discussed for the adult study population are results from the adult sample viewing the hypothetical cigarette package (as opposed to the sample viewing the hypothetical advertisement), unless otherwise noted.

difficult to look at measure) in the adult and youth samples. In young adults, the image also had a significant effect on all the salience measures (emotional reaction scale ($p<0.01$), cognitive reaction scale ($p<0.001$), and difficult to look at measure ($p<0.05$)).

The image had a significant effect ($p<0.05$) on recall of the warning statement at baseline compared to the control for adults and youth. The image also had a significant effect ($p<0.05$) on statement recall at 1 week follow-up in young adults. The image also showed some of the largest effect sizes for image recall (at baseline and at 1 week follow-up) in adults and young adults across the images proposed for use with this warning statement.

The image had a statistically significant effect ($p<0.05$) on youth intentions to not smoke in the next year, with 71.6 percent of youth viewing the image reporting that they would not be likely to smoke in the next year compared to 56.9 percent of youth viewing the text-only control.

As is discussed in further detail in section III.E of this document, three other images proposed for use with this warning statement, ''smoke at toddler,'' ''girl crying,'' and ''girl in oxygen mask,'' also had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). While several of the images proposed for use with this warning statement could effectively convey the negative health consequences of tobacco smoke exposure for nonsmokers (and in particular, children), we ultimately considered ''smoke approaching baby'' to have the strongest overall research results of the images proposed for use with this warning statement for multiple reasons.

First, two of the images that also showed significant effects on all the salience measures across the study populations, ''girl crying'' and ''girl in oxygen mask,'' were negatively associated with beliefs about the health risks of secondhand smoke exposure for nonsmokers in the adult sample. In other words, adults who viewed these images were less likely to believe that nonsmokers will suffer from negative health effects related to secondhand smoke exposure than adults who viewed the text-only control.

As described in section III.B of this document, we determined that the salience results from our research study are the most meaningful basis for making distinctions among the images given the design limitations of the research study, which exposed each participant to each image only once, and thus may not be able to accurately distinguish the relative effects of the images on more eventual outcomes, such as changes in beliefs, as reliably as their effects on more immediate emotional and cognitive reactions. However, the negative results observed on the secondhand smoke beliefs measure for the images ''girl crying'' and ''girl in oxygen mask'' were of concern, particularly given that the subject of the warning statement is the health risks of secondhand smoke exposure for children. Thus, ''smoke approaching baby'' was considered a preferable alternative to these two images.

Furthermore, ''smoke approaching baby'' was associated with youth reporting that they would be less likely to be smoking 1 year from now.

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 63) FDA received several comments supporting the use of the image ''smoke approaching baby,'' including comments from individuals, a public health advocacy group, and State and local public health agencies. Some of these comments indicated that this image is the best image of the ones proposed for use with this warning statement. One comment stated that the image will clearly inform parents that when they smoke in the presence of their children, their children will also be inhaling toxins, and another comment noted that the image realistically shows secondhand smoke exposure and health effects. Some comments noted that the image will deter smoking, with one comment noting that the depiction of an innocent baby will resonate with parents and cause them to think about their children's health before smoking.

(Response) We selected this image for use with this warning statement.

(Comment 64) FDA also received some comments expressing support for the diversity reflected in the image. One comment stated that the image will appeal to different age and other demographic groups, while another comment noted that the child in the image could be African-American, Hispanic, Latino, Native American, and/or Native Hawaiian or Pacific Islander, and suggested that the image could resonate with a variety of important population subgroups. The comment also noted that Latino parents say the health of their children is a motivating factor in their decision to quit smoking.

(Response) It is important to have a diverse set of images that communicate with a wide range of audiences, including a variety of population subgroups. In order to ensure that the final set of required warnings effectively communicates risk information to a diverse range of audiences, we selected a set of nine required warnings, including the image ''smoke approaching baby,'' that includes a variety of human images that are broadly representative of the overall population.

(Comment 65) As mentioned in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example, it was rated highly on its ease of comprehension and induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control in one submitter's study.

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 66) FDA also received some comments critical of the image ''smoke approaching baby.'' These comments suggested that the child does not appear to be suffering harms to his health and/or looks too healthy. One of these comments also stated that the image was associated with youth reporting that they would be more likely to be smoking 1 year from now, and advised against its use.

(Response) We do not agree that the image does not depict the health hazards of secondhand smoke. Graphic depictions of the visible effects of disease are not the only way of communicating the health risks of secondhand smoke for children (*see* Ref. 11), some of which (such as impaired lung growth), are not necessarily externally visible in a photograph of a child exposed to secondhand smoke. Furthermore, it is important to keep in mind that the image is not used in isolation, but accompanies the textual warning statement, which provides additional context for what is shown. As evidenced by the significant effects the image had on the salience measures compared to the text-only control across the populations participating in FDA's research study, the required warning depicts the health consequences of

secondhand smoke exposure in a manner that has an impact on both smokers and potential smokers. Thus, we conclude that the required warning effectively conveys the message that exposure to tobacco smoke is harmful for children.

We also note that the comment stating that the image was associated with youth reporting that they would be more likely to be smoking 1 year from now is incorrect. In fact, the image had a statistically significant effect on decreasing youth intentions to smoke (*see* Ref. 49 at p. 4–4; *see also* Ref. 50). As stated previously, 71.6 percent of youth viewing this image reported that they would *not* be likely to smoke in the next year, compared to 56.9 percent of youth viewing the text-only control.

3. ''WARNING: Cigarettes Cause Fatal Lung Disease''

We selected the image which appears on pages 25 and 26 of the document ''Proposed Required Warning Images,'' referred to as ''healthy/diseased lungs,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). The image had the numerically largest effects of the images proposed for use with this warning statement on the salience measures. As discussed in section III.B of this document, these salience impacts are important, as the research literature suggests that they are likely to be related to behavior change.

The image also showed some of the largest effect sizes for image recall (at baseline and at 1 week follow-up) in adults and youth across the images proposed for use with this warning statement.

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 67) FDA received a large number of comments supporting the use of the image ''healthy/diseased lungs,'' including comments from individuals, public health advocacy groups, medical organizations, academics, State and local public health agencies, and health care professionals. Many comments indicated that this image is the best image for use with this warning statement, with one stating that the image dramatically depicts a health consequence of smoking, and another noting that it was appropriately gripping and compelling.

Several comments noted that, based on FDA's research results, this image is the clear choice among the four images proposed by FDA for use with this warning statement. Some comments noted that similar images have been used effectively in other countries that require graphic health warnings on cigarette packages. One comment noted that this image could reach a younger audience, and hopefully prevent them from starting to smoke.

(Response) We selected this image for use with this warning statement.

(Comment 68) As mentioned in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. The submitter concluded that this image was the most effective of the images proposed for use with this warning statement. Another comment also submitted research suggesting that this image was the highest rated for potential effectiveness among the set of images proposed for use with this warning statement. Another submitter showed that, in a survey, respondents rated this image as one of the most effective of the 36 proposed images for encouraging smokers to quit smoking. The image was also identified in a survey of high school students as one of the ''top three'' proposed required warnings (out of 36) in another submitter's study.

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 69) FDA also received some comments critical of the image ''healthy/diseased lungs.'' One comment noted that the image was ''too gross to be effective,'' while several comments expressed the opposite belief, with some suggesting that the diseased pair of lungs should be more damaged.

(Response) The image ''healthy/diseased lungs'' is an appropriate image that effectively conveys the negative health consequences of smoking. While, as reflected in the above summary, some comments expressed a belief that the image of the diseased lung is ''too gross'' and some expressed a belief that the image is too healthy in appearance, the image effectively evoked emotional and cognitive reactions in viewers in FDA's research study, which in turn suggests that the image has the potential to promote greater awareness of the health risks of smoking and motivate positive behavioral outcomes, including an increased likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

4. ''WARNING: Cigarettes Cause Cancer''

We selected the image which appears on pages 33 and 34 of the document ''Proposed Required Warning Images,'' referred to as ''cancerous lesion on lip,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). The image had the numerically largest effects of the images proposed for use with this warning statement on the emotional reaction scale and had the numerically largest effects on the cognitive reaction scale in young adults and youth. As discussed in section III.B of this document, these salience impacts are important, as the research literature suggests that they are related to behavior change.

The image also had a significant impact ($p<0.05$) on beliefs about the health risks of smoking for smokers, and a significant impact ($p<0.01$) on beliefs about the health risks of secondhand smoke exposure for nonsmokers relative to the text-only control in the adult sample that viewed a hypothetical advertisement containing the proposed required warning.

The image also showed some of the largest effect sizes for image recall (at baseline and 1 week follow-up) in adults and youth across the images proposed for use with this warning statement, though it showed lower correct recall of the warning statement compared to the control in adults at 1 week follow-up (68.3 percent versus 85.1 percent). However, recall of the statement was generally high at 1 week follow-up among study participants who viewed this image (ranging from 68.3 percent to 77 percent), and, based on the scientific literature, we conclude that repetitive viewing of the required warning is likely to increase recall. As explained in section III.C of this document, we gave greater weight to

outcomes on the salience measures than to outcomes on the recall measures.

As is discussed in further detail in section III.E of this document, another image proposed for use with this warning statement, ''deathly ill woman,'' also had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three samples (adults, young adults, and youth). While we agree that this image, similar to the selected image of ''cancerous lesion on lip,'' is a very strong image that effectively conveys the negative health consequences of smoking, we ultimately chose ''cancerous lesion on lip'' for use with this warning statement for several reasons.

First, ''cancerous lesion on lip'' was the only image among the images proposed for use with this warning statement that had a positive impact on beliefs about the health risks of smoking and secondhand smoke exposure in one of the study samples (adults viewing a hypothetical advertisement).

Furthermore, as is stated in several comments (see the following paragraphs), the selected image, ''cancerous lesion on lip,'' is likely to have particular relevance for youth. As explained in some of these comments, the research literature suggests that youth are likely to relate to and be susceptible to cigarette warnings depicting the negative short-term impacts of smoking on their personal appearance, including their lips and teeth (Ref. 53).

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 70) FDA received a large number of comments supporting the use of the image ''cancerous lesion on lip,'' including comments from individuals, public health advocacy groups, a medical organization, academics, State and local public health agencies, and health care professionals. Several comments suggested that FDA should use this image because it has a very high potential to reach consumers and positively influence their behavior.

A few comments also specifically addressed the benefits of using an image that shows the public that cigarettes cause oral cancers, noting that public awareness of this negative health consequence is low, and that many smokers and nonsmokers only relate cigarettes to lung cancer (*see also* section II.C of this document regarding consumers' lack of knowledge regarding the health risks of smoking).

Multiple comments also noted that, based on FDA's research results, this image was the best choice among the four images proposed for use with this warning statement, significantly outperforming ''white cigarette burning'' and ''red cigarette burning,'' and slightly outperforming ''deathly ill woman.''

(Response) We selected this image for use with this warning statement.

(Comment 71) Several comments noted that the image could be especially effective with younger audiences and could positively influence such audiences by illustrating how the health effects caused by smoking negatively affect their physical appearance. The comments indicated that adolescents can relate to and will be susceptible to this message.

(Response) We agree with these comments. It is important to include content in the required warnings that is relevant to youth. The image ''cancerous lesion on lip'' has the potential to positively impact youth behavior, in addition to adult and young adult behavior.

(Comment 72) As mentioned in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. The submitter concluded that this image, along with ''deathly ill woman,'' was one of the most effective of the images proposed for use with this warning statement. In addition, this image was rated as the most effective of the 36 proposed images in another submitter's survey of comparative effectiveness of the images in helping smokers quit. It was also the highest rated image among the set of images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images, and was identified by high school students as one of the ''top three'' proposed required warnings (out of 36) in another submitter's study.

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 73) FDA also received some comments critical of the image ''cancerous lesion on lip.'' Two comments indicated that the image was ''too gross'' to be effective, while another comment stated that it borders on the offensive. In contrast, some comments suggested that the image should be more graphic. Another comment suggested that oral cancer was an odd choice of cancers to depict in the graphic warning.

(Response) We disagree with these comments. With respect to the comments stating that the image was ''too gross'' or that it was offensive, the research literature indicates that images that evoke strong emotional reactions can promote greater awareness and better recollection of the health risks of smoking and can increase the likelihood smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

With respect to the suggestion that the image is not graphic enough, as discussed previously, this image had a highly significant effect ($p<0.001$) on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth), which in turn suggests that the image has the potential to motivate positive behavior change (*Id.*).

Furthermore, the choice of cancers depicted in the required warning is appropriate, and will help inform the public that cigarettes cause oral cancers, and thus increase public awareness of the negative health consequences of smoking.

5. ''WARNING: Cigarettes Cause Strokes and Heart Disease''

We selected the image which appears on pages 39 and 40 of the document ''Proposed Required Warning Images,'' referred to as ''oxygen mask on man's face,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). The image had the numerically largest effects of the images proposed for use with this warning statement on the emotional reaction scale and the difficult to look at measure in all the study populations. These impacts are important, as the research literature suggests that graphic warnings that evoke responses of this kind are

likely to increase awareness of the health risks of smoking and increase the likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

The image also showed some of the largest effect sizes for image recall (at baseline and 1 week follow-up) in adults and youth across the images proposed for use with this warning statement.

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 74) FDA received a large number of comments supporting the use of the image ''oxygen mask on man's face,'' including comments from individuals, medical organizations, public health advocacy groups, health care professionals, State public health agencies, and academics. Many of these comments indicated that this image is the best image for use with this warning statement, while some also noted that the image will make smokers think twice about continuing to smoke. Some comments also noted that the image is beneficial in that it will inform the public of negative consequences of smoking aside from lung disease.

Some comments also noted that, based on FDA's research results, this image was the best choice for use with this warning statement, noting that it elicited the highest scores on the emotional reaction scale of the images tested for use with this statement in FDA's research study.

(Response) We selected this image for use with this warning statement.

(Comment 75) As described in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. The submitter concluded that this image was the most effective of the images proposed for use with this warning statement. In another submitter's study, this image was the highest-rated of the FDA-proposed images for use with this warning statement; however, this study also evaluated two images used with similar warning statements in other countries (one of open heart surgery, one of a bloody brain), and noted that they rated higher than FDA's proposed images.

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 76) FDA also received some comments critical of the image ''oxygen mask on man's face.'' One comment noted that the image was ''too gross to be effective,'' and one comment stated that the image should feature a younger person to highlight the fact that heart attacks and stroke can occur in young smokers as well as in older smokers.

(Response) The image ''oxygen mask on man's face'' is an appropriate image that effectively conveys the negative health consequences of smoking. We do not agree with the statement that the image is ''too gross to be effective;'' the image effectively elicited emotional and cognitive reactions in viewers in our research study, which in turn suggests that the image has the potential to promote greater awareness of the health risks of smoking and motivate positive behavioral outcomes, including an increased likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

While we agree with the statement in the comment that heart disease and strokes can occur in young smokers as well as in older smokers, the selected required warning will effectively communicate with a range of audiences, including consumers of different ages. As described previously, ''oxygen mask on man's face'' had a significant effect ($p<0.001$) on all the salience measures (emotion measures, cognition measures, and difficult to look at measure) in all three study populations (adults, young adults, and youth). We considered the variety and diversity reflected in the images in making selection decisions, and took into account the importance of selecting a set of required warnings that includes a diversity of styles (*e.g.,* photographic versus illustrative), themes, and human images (*e.g.,* race, gender, age). While the person shown in this image is an older man, some of the images show younger people. Overall, the nine selected required warnings will effectively communicate to a wide range of consumers, including both young and older smokers.

6. ''WARNING: Smoking During Pregnancy Can Harm Your Baby''

We selected the image which appears on pages 45 and 46 of the document ''Proposed Required Warning Images,'' referred to as ''baby in incubator,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). The image had the numerically largest effects of the images proposed for use with this warning statement on the salience measures. As discussed in section III.B of this document, these salience impacts are important, as the research literature suggests that they are likely to be related to behavior change.

The image had a significant effect ($p<0.01$) on recall of the warning statement at baseline compared to the text-only control in youth. The image also had a significant effect ($p<0.05$) on statement recall at follow-up in young adults, and showed the largest effect sizes for image recall (at baseline and 1 week follow-up) in adults and youth across the images proposed for use with this warning statement.

The image had a significant impact ($p<0.05$) on beliefs about the health risks of smoking for smokers in adults, although it had a negative significant impact ($p<0.05$) on beliefs about the health risks of smoking for smokers in youth. Thus, the results on this beliefs measure were mixed for ''baby in incubator.'' However, given the strength of the effects observed for this image on the salience measures, the required warning that includes the ''baby in incubator'' image is likely to increase awareness of the health risks of smoking and increase the likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 77) FDA received a number of comments supporting the use of the image ''baby in incubator,'' including comments from individuals, a community organization, a public health advocacy group, health care professionals, a State public health agency, and academics. Several of these comments indicated that this image is the best image for use with this warning statement, with some noting that the image effectively shows how smoking during pregnancy can damage a baby's health. One comment noted that the image could stimulate discussion about how smoking affects pregnancy among youth.

One comment also noted that the image ''baby in incubator'' outperformed the other image proposed for use with this warning statement in FDA's research study on the key criteria that have proven most meaningful.

(Response) We selected this image for use with this warning statement.

(Comment 78) As described in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. The submitter concluded that this image was the most effective of the images proposed for use with this warning statement. However, in another submitter's study, this image was evaluated against images used in other countries, one of which was very similar in composition to ''baby in incubator'' but which was a photograph rather than a graphic illustration. In that submitter's study, the photographic image was rated significantly higher than ''baby in incubator.''

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 79) FDA also received a number of comments critical of the image ''baby in incubator.'' The majority of these comments objected to the graphic illustration style used for the image, with some submitters approving of the concept but stating that a photograph would be more impactful, and some indicating that the style is inappropriate, either because it downplays the seriousness of the risk described in the required warning or because it would inappropriately appeal to youth without discouraging them from smoking.

Some comments indicated that the lettering style used in the image was difficult to read, and one comment stated that the results from FDA's research study for this image, while better than the results for the other image proposed for use with this warning statement (''pacifier & ashtray''), were not compelling.

One comment stated that the image bordered on the offensive.

(Response) The image ''baby in incubator'' is an appropriate image that effectively conveys the negative health consequences of smoking. As discussed in section III.C of this document, we are aware that many comments received in the docket expressed concern about the use of graphic illustration style images and expressed a belief that this style was not strong enough to elicit appropriate reactions. However, as discussed in section III.C of this document, we disagree with the contention that the use of graphic illustration style images is categorically inappropriate. As the results from our research study demonstrate, the ''baby in incubator'' image effectively elicited emotional and cognitive reactions, showing a highly significant effect ($p<0.001$) on these measures in all study populations, which in turn suggests that the image has the potential to promote greater awareness of the health risks of smoking and motivate positive behavioral outcomes, including an increased likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

In addition, based on the study results, we also do not agree that the image is inappropriately offensive or that our research results for this image are not compelling. Based on the overall feedback received, we also disagree that the text in the proposed warning is difficult to read.

7. ''WARNING: Smoking Can Kill you''

We selected the image which appears on pages 49 and 50 of the document ''Proposed Required Warning Images,'' referred to as ''man with chest staples,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). The image had the numerically largest effects of the images proposed for use with this warning statement on the salience measures. As discussed in section III.B of this document, these salience impacts are important, as the research literature suggests that they are likely to be related to behavior change.

The image was also associated with higher intentions to quit smoking compared to the text-only control ($p<0.05$) in adults.

The proposed required warning featuring the ''man with chest staples'' image showed some of the largest effect sizes for image recall among the images proposed for this warning statement at baseline in all study populations and at 1 week follow-up in young adults and youth.

Young adults viewing the image had significantly lower recall of the warning statement than those viewing the text-only control at baseline (76.2 percent versus 92.3 percent) and 1 week follow-up (78.9 percent versus 91.3 percent). However, recall of the statement was generally high at baseline and follow-up among study participants who viewed this image (ranging from 76.2 percent to 90.4 percent), and repetitive viewing of the required warning is likely to increase recall. As explained in section III.C of this document, we gave greater weight to outcomes on the salience measures than to outcomes on the recall measures.

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 80) FDA received a large number of comments supporting the use of the image ''man with chest staples,'' including comments from individuals (including former smokers), public health advocacy groups, medical organizations, health care professionals, State and local public health agencies, and academics. Many of these comments indicated that this image is the best image for use with this warning statement, while some also noted that the image is appropriately attention-grabbing or powerful and that it will make smokers think twice about continuing to smoke, or help them smoke less. Some comments also noted that the image is an excellent way of driving home the message that smoking can kill you. One comment stated that the image is a strong, solid concept that has been used effectively in other countries that require graphic health warnings on cigarette packages.

Some comments stated that, based on FDA's research results, this image is the best choice for use with this warning statement, noting that it elicited the highest scores on the emotional reaction scale of the images tested for use with this statement in FDA's research study, and had other positive results.

(Response) We selected this image for use with this warning statement.

(Comment 81) As described in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example,

in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. In another submitter's study, it was noted that, based on respondents' rating and ranking of this image's effectiveness, the image clearly stands out as the highest rated of the images FDA proposed for use with this warning statement.

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 82) FDA also received some comments critical of the image ''man with chest staples.'' One comment stated that the image was ''too gross to be effective,'' while another stated the image ''offend[s] against human dignity.'' A few comments suggested that the person in the image should look worse (*e.g.,* paler, weaker, thinner, like he had suffered more), and some comments suggested the person's death should be more clearly tied to smoking by the image. One comment indicated that persons unfamiliar with an autopsy may not understand the image.

(Response) The image ''man with chest staples'' is an appropriate image that effectively conveys the negative health consequences of smoking. We do not agree that the image ''is too gross to be effective'' or that it ''offend[s] against human dignity;'' the image shows a realistic outcome of the negative health consequences caused by smoking, and effectively elicited emotional and cognitive reactions in viewers in our research study. This in turn suggests that the image has the potential to promote greater awareness of the health risks of smoking and motivate positive behavioral outcomes, including an increased likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

Viewers will understand that the image shows someone who has died from a smoking-related cause. Although we agree that not all viewers will necessarily be familiar with an autopsy scar, it is important to keep in mind that the image is not used in isolation, but accompanies the textual warning statement, which provides additional context for what is shown. The results observed in our research study suggest that viewers from all age groups understood and reacted to this image in desirable ways. The figure shown is appropriate; although some of the negative health consequences of smoking may lead to the effects on appearance suggested in the comments (*e.g.,* significant disease-related weight loss), other consequences, such as heart attacks, can kill smokers without first causing these effects.

8. ''WARNING: Tobacco Smoke Causes Fatal Lung Disease in Nonsmokers''

We selected the image which appears on pages 57 and 58 of the document ''Proposed Required Warning Images,'' referred to as ''woman crying,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on the emotional reaction scale in all three study populations (adults, young adults, and youth). It also showed significant effects on the difficult to look at measure in all study populations (adults ($p<0.01$), young adults ($p<0.001$), and youth ($p<0.001$)), and significant effects on the cognitive reaction scale in all study populations (adults ($p<0.05$), young adults ($p<0.001$), and youth ($p<0.001$)). This image was the only image proposed for use with this warning statement that showed significant effects on all the salience measures in our research study.

The image also had a significant impact ($p<0.05$) on beliefs about the health risks of smoking for smokers in young adults.

The proposed required warning that included this image also showed the largest effect sizes for image recall (at baseline and 1 week follow-up) in adults, young adults, and youth across the images proposed for this warning statement. Youth viewing the image had significantly lower recall of the warning statement than those viewing the text-only control at baseline (52.4 percent versus 68.9 percent). However, recall of the statement was generally high among study participants who viewed this image, and repetitive viewing of the required warning is likely to increase recall. As explained in section III.C of this document, we gave greater weight to outcomes on the salience measures than to outcomes on the recall measures.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 83) FDA received several comments supporting the use of the image ''woman crying,'' including comments from individuals (including former smokers) and public health advocacy groups. Some of these comments indicated that this image is the best image of the ones proposed for use with this warning statement. One comment stated that the image stood out as particularly effective among the proposed required warnings because it shows the devastating effects secondhand smoke can have on people who have tried to protect themselves by not smoking, and indicated that the image will remind smokers that they are harming their loved ones and others around them as well as themselves. Others noted that the image sends a powerful message.

One comment indicated that the image outperformed the other images proposed for use with this warning statement on the emotional reaction scale and the difficult to look at measure in FDA's research, and noted that it appears to be a cut above the other images.

(Response) We selected this image for use with this warning statement.

(Comment 84) One comment approved of the diversity reflected in the image (which shows an African-American woman).

(Response) We agree that it is beneficial to have a diverse set of images that communicate with a wide range of audiences, including a variety of population subgroups. In order to ensure that the final set of required warnings effectively communicates risk information to a diverse range of audiences, we selected a set of nine required warnings, including the image ''woman crying,'' that includes a variety of human images that are broadly representative of the overall population.

(Comment 85) As described in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example, this image induced relatively greater worry and led to higher ratings of feeling discouraged from wanting to smoke than a text-only control in one submitter's study.

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 86) FDA also received some comments critical of the image ''woman crying.'' One comment indicated that the image borders on the

offensive, while another stated it is too sensational to be effective.

Other comments suggested that the image did not directly portray a health consequence of secondhand smoke, or that the image is not clearly tied to secondhand smoke. One comment also suggested that the image should not be used because it did not have an impact on beliefs about the health harms of secondhand smoke or on quit intentions in FDA's research study.

(Response) We disagree with these comments. The image ''woman crying'' is an appropriate image that effectively conveys the negative health consequences of smoking. We do not agree that the image is offensive or too sensational; the image is a realistic portrayal of how the negative health consequences caused by exposure to secondhand smoke can affect people. It effectively elicited emotional and cognitive reactions in those who viewed it in our research study, which in turn suggests that the image has the potential to promote greater awareness of the health risks of smoking and motivate positive behavioral outcomes, including an increased likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

We do not agree that the image does not depict a health consequence of secondhand smoke. Graphic depictions of the visible effects of disease are not the only way of communicating the health risks of secondhand smoke exposure (*see* Ref. 11). The negative health consequences caused by secondhand smoke exposure, including fatal lung disease, have many dimensions, including emotional suffering. This image highlights that dimension. Furthermore, it is important to keep in mind that the image is not used in isolation, but accompanies the textual warning statement, which provides additional context for what is shown. As evidenced by the image's significant impact on the salience measures across the populations participating in our research study, the proposed required warning effectively depicts the health consequences of secondhand smoke exposure, including the suffering endured by those experiencing these health consequences.

9. ''WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health''

We selected the image which appears on pages 67 and 68 of the document ''Proposed Required Warning Images,'' referred to as ''man I Quit t-shirt,'' for use with this warning statement.

In our research study, the image had a statistically significant effect on the emotional reaction scale in young adults ($p<0.05$), and on the cognitive reaction scale in adults ($p<0.05$), young adults ($p<0.01$), and youth ($p<0.001$).

The proposed required warning that included this image also showed the largest effect sizes for image recall (at baseline and 1 week follow-up) in adults, young adults, and youth across the images proposed for this warning statement.

Although this image, along with the other images proposed for use with this warning statement, did not elicit the magnitude of reactions on the salience measures (emotional reaction scale, cognitive reaction scale, difficult to look at measure) that some of the images proposed for use with other warning statements did, this is likely a result of the information being conveyed in the warning statement, which emphasizes the positive health benefits of quitting smoking. The content of this required warning is not expected to arouse the same level of response on some of the salience measures as the other messages.

However, the research literature suggests that warnings that focus on the benefits of quitting are effective at encouraging cessation, and suggests that positive, self-efficacy messages can be used effectively as one component of graphic health warnings to increase smokers' motivations and confidence about quitting (Ref. 40 at pp. 35, 39–41). The research literature also highlights the importance of including one or more warnings that provide solutions, such as the ''man I Quit t-shirt'' required warning, in a set of warnings conveying the negative health consequences of smoking. Specifically, the literature recommends that, in addition to communicating the health risks of smoking, some warnings should also provide information on how to avoid these risks (*i.e.,* by quitting), in order to optimize the effectiveness of the overall set of warning messages (*see* Ref. 48 and Ref. 40 at p. 37).

As is discussed in further detail in section III.E of this document, another image proposed for use with this warning statement, ''cigarettes in toilet bowl,'' also had significant effects on the emotional reaction scale in some study populations and on the cognitive reaction scale, as well as showing positive effects on other study measures. While this image, similar to the selected image (''man I Quit t-shirt''), could be effectively used with this warning statement, we ultimately selected ''man I Quit t-shirt'' for use with this warning statement based on a consideration of multiple factors, including the feedback received in the docket, which is discussed in the comment summaries in the following paragraphs and in section III.E of this document.

Furthermore, as noted in section III.A of this document, in order to ensure that the final set of required warnings effectively communicates risk information to a diverse range of audiences, we selected a set of nine required warnings, including the image ''man I Quit t-shirt,'' that includes a variety of human images that are broadly representative of the overall population. The image ''man I Quit t-shirt'' contributes to the variety seen in the final set of images by picturing a man who is younger than the men in the other required warning images. Additionally, as reflected in the comment summary, the man shown in the image is perceived by many viewers as strong and ''macho,'' suggesting that the image has the potential to reach and effectively communicate with a demographic group that has been heavily targeted by tobacco industry cigarette advertising (*see* Ref. 54 at p. 151). The depiction of men as strong, powerful, macho, rugged, and independent, and the association of these characteristics with cigarette brands, has long been a prominent theme in tobacco industry advertising (*Id.* at p. 151), and targeted marketing efforts by the tobacco industry have led to greater smoking uptake and lower cessation rates in targeted subgroups (*Id.* at p. 211).

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 87) FDA received a number of comments supporting the use of the image ''man I Quit t-shirt,'' including comments from individuals, public health advocacy groups, medical organizations, and State and local public health agencies. Many of these comments indicated that this image is the best image of the ones proposed for use with this warning statement. Several of the comments discussed specific favorable aspects of the image or potential effects of the image, including that the image models a positive behavior, is compelling, and that it will encourage others to quit. Several comments believed that the image could reach a critical demographic group by showing a younger, ''cool,'' ''macho'' man and suggesting that it is manly and/or cool to quit smoking. Some comments also suggested that the image is positive in that it shows that quitting is a heroic decision.

(Response) We selected this image for use with this warning statement.

(Comment 88) As described in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. In one submitter's study, the image ''man I Quit T-shirt'' was the highest rated of the images proposed by FDA for use with this warning statement among adults. This study also tested a version of the required warning that had been manipulated to add a quitline number; this version was rated and ranked as the most effective warning overall among study participants. In another submitter's study, this image was rated highly on its ease of comprehension, but led to lower worry relative to a text-only control (but as the researcher noted, the message in this warning is reassuring: ''Quitting smoking now greatly reduces serious risks to your health'').

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 89) FDA also received some comments critical of the image ''man I Quit t-shirt.'' Some comments indicated that the image does not convey a health consequence of smoking, while one indicated that the text was difficult to read. One comment also noted that the image failed to show an effect on some measures in FDA's research study, and another indicated that the image is banal.

(Response) We disagree with these comments. The image ''man I Quit t-shirt'' is an appropriate image. Consumers can be educated about the negative health consequences of smoking in a variety of ways. While the other required warnings discuss and portray the consequences of starting or continuing to smoke (which has been shown to be one effective way to educate consumers), another method of increasing awareness and knowledge about the negative consequences of a behavior is to disseminate messages that discuss the positive health benefits of refraining from a behavior (Ref. 55). Studies attest to the potential effectiveness of warnings that adopt such an approach (Ref. 40 at p. 35). Accordingly, the warning statement used in this required warning, ''Quitting smoking now greatly reduces serious risks to your health,'' is framed in a positive manner, discussing the health benefits of ceasing to smoke, and the image is consistent with this text. This required warning, particularly as part of the overall set of required warnings, will help educate consumers about the negative health consequences of smoking and help encourage positive behavior (*see* Ref. 40 at pp. 35 and 40).

Based on the overall feedback received and the results from our research study, we also disagree that the text in the proposed warning is difficult to read or that the image is banal.

10. Image for Advertisements With a Small Surface Area

In addition to proposing 36 required warnings for use on cigarette packages and in cigarette advertisements in the NPRM, we also proposed two other color graphics for use solely in advertisements with a small surface area of less than 12 square inches (75 FR 69524 at 69539). As we explained in the NPRM, these two proposed color graphics differ in their composition from the other proposed images in that the details of these two color graphics should be clear, conspicuous, and legible even when the image is reduced in size to occupy 20 percent of a surface with an area of less than 12 square inches (75 FR 69524 at 69535). We proposed that whichever of these options was selected would be used in combination with one of the nine textual statements only in advertisements with a small surface area (*i.e.,* less than 12 square inches). However, as we noted in the NPRM, even an advertisement with a relatively small surface area would need to be large enough so that the required graphic and accompanying textual warning statement are clear, conspicuous, and legible (75 FR 69524 at 69539).

We selected the image which appears on page 75 of the document entitled ''Proposed Required Warning Images'' for use with the textual warning statements solely in advertisements with a small surface area (defined as less than 12 square inches). This image depicts a black exclamation mark enclosed within a red equilateral triangle.

As stated previously, FDA proposed two images for use solely with the textual warning statements in advertisements with a small surface area; the selected image described in the previous paragraph and an image of a burning cigarette enclosed in a red circle with a red bar across it. We did not receive any comments on either of the proposed images.

Versions of both of these images have been used in other contexts. For example, the image of an exclamation mark enclosed within a triangle is often used to draw attention to a warning of danger or hazards that could result in personal injury or a threat to health (*see, e.g.,* 16 CFR 1211.15, 16 CFR 1407.3; 16 CFR 1500.19; and Ref. 56). The image of a burning cigarette enclosed in a red circle with a red bar across it is the international ''No Smoking'' symbol (Ref. 56) and is often used on signs and placards to denote an area where smoking is prohibited (*see, e.g.,* 14 CFR 23.853, 49 CFR 374.201).

In light of the other contexts in which the two proposed images are used, we selected the image of the exclamation mark enclosed within a red equilateral triangle, as we believe this image is more appropriate than the other proposed image for use in the required warnings. As stated, this image is commonly used to draw attention to a warning of danger which could result in personal injury or a threat to health, which is consistent with its purpose in cigarette advertisements with a small surface area. Many consumers have likely been exposed to similar symbols in other contexts and, as a result, are likely to recognize and understand that the image is drawing attention to a warning of a threat to health.

E. Non-Selected Images

This section discusses the 27 color graphic images that we proposed but have not selected for use at this time, and the factors that influenced the decision not to use each image, including the research results for the images, the comments received in the docket, and the relevant scientific literature.

Consistent with the discussion of selected images in section III.D of this document, the images are referred to in this section by the pages on which they appear in the ''Proposed Required Warning Images'' document and by the descriptive names used in the study report (Ref. 49, study report) summarizing the results of FDA's research study.

1. ''WARNING: Cigarettes Are Addictive''

As discussed in section III.D of this document, we selected the image ''hole in throat'' for use with the statement, ''WARNING: Cigarettes are addictive.'' We proposed three other images for use with this statement: ''cigarette injection,'' which appears on pages 3 and 4 of the document ''Proposed Required Warning Images;'' ''red puppet,'' which appears on pages 5 and

6 of the document ''Proposed Required Warning Images;'' and ''woman in rain,'' which appears on pages 7 and 8 of the document ''Proposed Required Warning Images.''

Cigarette Injection. The image ''cigarette injection'' had strong overall research results in FDA's research study, including significant effects on the emotional and cognitive reaction scales in all three study populations and significant effects on the difficult to look at measure in adults and young adults. It also showed higher correct recall of the warning statement compared to the control in adults and young adults at baseline, and was associated with higher intentions to quit compared to the control for young adults. The image also had a positive significant impact on adult beliefs about the health risks of smoking for smokers in adults viewing the hypothetical cigarette package with the proposed required warning, although it had a negative significant impact on this same measure in adults viewing the hypothetical cigarette advertisement featuring this proposed required warning.

The image selected for use with this warning statement, ''hole in throat,'' had numerically larger effects than this image (''cigarette injection'') on the salience measures (emotional and cognitive reaction scales, difficult to look at measure) in all three study populations. As discussed in section III.B of this document, the research literature suggests that the salience measures used in FDA's study are likely to be related to behavior change.

In addition, the selected image, ''hole in throat,'' enhanced the diversity of the overall set of selected images by helping ensure the human images broadly represent the U.S. population. Although ''cigarette injection'' offered variety in terms of style in that it uses a graphic illustration style as opposed to the photographic style used in most of the selected images, this style is incorporated in the final set of required warnings with the image used for the warning statement ''Smoking during pregnancy can harm your baby.''

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 90) FDA received several comments that supported the use of the image ''cigarette injection,'' including comments from individuals, public health advocacy groups, and a State public health agency. Some of the comments stated that the image would be an effective smoking deterrent. Several of the comments noted that the image would help smokers understand that, although cigarettes are legal products, they are just as addictive as illegal drugs like heroin. One comment indicated that the image would be particularly effective with underage smokers.

FDA also received several comments that opposed the use of the image ''cigarette injection.'' Many of these comments objected to the graphic illustration style used in the image, with some stating it would be ineffective or less effective than a photographic image, and some indicating it would detract from the seriousness of the message being conveyed. Some comments also expressed concern that the style would inappropriately appeal to youth without deterring them from smoking.

A few comments also objected to the comparison of legal cigarette products with illegal drugs, with one comment indicating this downplayed the seriousness of intravenous drug use, and another comment noting that the analogy of cigarette use to heroin use could cause consumers to discount the message if they believe that cigarette and heroin use are not comparable.

Some comments also stated that the image could be misunderstood or was too abstract, and one comment stated that the image does not illustrate adverse health effects.

One comment noted that the proposed required warning featuring the ''cigarette injection'' image was not rated highly on its ease of comprehension in a research study the submitter conducted on the 36 proposed required warnings, though it did show a significant effect on worry and feeling discouraged from wanting to smoke relative to a text-only control.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''hole in throat'' for the reasons given in section III.D of this document.

Red puppet. In FDA's research study, the image ''red puppet'' had significant effects on the emotional and cognitive reaction scales in all three study populations. It also showed higher correct recall of the warning statement compared to the control in young adults at 1 week follow-up.

However, the selected image, ''hole in throat,'' had numerically larger effects than this image on the salience measures (emotional reaction scale, cognitive reaction scale, difficult to look at measure) in all three study populations. In addition, looking across the different measures used in the research study, both the image ''hole in throat'' and the image ''cigarette injection'' had stronger overall research results than this image.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 91) FDA received several comments that supported the use of the image ''red puppet,'' including comments from individuals, a public health advocacy group, and from State and local public health agencies. Some of the comments stated that the image is likely to be effective, and one stated that it would impact underage smokers. Another noted that it was a clever image.

FDA also received several comments that opposed the use of the image ''red puppet.'' Some of these comments stated that the image style was less effective than a photographic image. One comment expressed concern that the style would inappropriately appeal to youth without deterring them from smoking.

Several comments expressed concern that the image would not be understood by some consumers, including youth and some racial and ethnic minorities, who might not understand and identify with the picture of a marionette, or draw the analogy between the manipulation suggested by the image of the puppet and addiction.

A few comments stated the image does not convey a health consequence of smoking, while one comment stated that the results from FDA's research study for this image did not support its selection from among the images proposed for use with this warning statement.

Three comments noted that the proposed required warning featuring the ''red puppet'' image was not highly rated in research studies conducted by the submitters. One comment noted that the image did not increase worry relative to a text-only label or discourage respondents from smoking relative to a text-only label in the submitter's study, while two others noted that the image was ranked as one of the least effective of the proposed images by respondents in the submitters' studies.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''hole in throat'' for the reasons given in section III.D of this document.

Woman in rain. In FDA's research study, the image ''woman in rain'' had a significant effect on the difficult to look at measure in adults and young adults. The image also had a significant impact on adult beliefs about the health risks of smoking for smokers compared to the control.

Looking across the different measures used in FDA's research study, this image was relatively less effective than other images proposed for this warning statement, including the image selected for use in the required warnings ''hole in throat.''

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 92) FDA received multiple comments that supported the use of the image ''woman in rain,'' including comments from individuals, a community organization, and a State public health agency. Some of the comments stated that the image is likely to be effective, and one stated that smokers would be able to relate to the image.

FDA also received a number of comments that opposed the use of the image ''woman in rain.'' Some of these comments stated that the image would not be effective and is not emotionally arousing, while some stated that it shows a very weak harm (*i.e.,* standing in the rain). Another comment stated that the image makes smoking seem like a normal behavior.

Several comments expressed concern that the image would not be understood by consumers, indicating it was too vague in nature and requires a high analytical ability to understand.

Several comments stated the image does not convey a health consequence of smoking, while three comments stated that the results from FDA's research study for this image did not support its selection from among the images proposed for use with this warning statement.

Two comments noted that the proposed required warning featuring the ''woman in rain'' image was not highly rated in research studies conducted by the submitters. One comment noted that the image was not rated highly on its ease of comprehension and did not increase worry relative to a text-only label or discourage respondents from smoking relative to a text-only label in the submitter's study, while another noted that the image was ranked as one of the least effective of the 36 proposed images by respondents in the submitter's study.

(Response) We did not select this image for use in a required warning and instead have selected the image ''hole in throat'' for the reasons given in section III.D of this document.

2. ''WARNING: Tobacco Smoke Can Harm Your Children''

As discussed in section III.D of this document, we selected the image ''smoke approaching baby'' for use with the statement, ''WARNING: Tobacco Smoke Can Harm Your Children.'' FDA proposed five other images for use with this statement: ''Smoke at toddler,'' which appears on pages 11 and 12 of the document ''Proposed Required Warning Images;'' ''smoke at baby,'' which appears on pages 13 and 14 of the document ''Proposed Required Warning Images;'' ''girl crying,'' which appears on pages 15 and 16 of the document ''Proposed Required Warning Images;'' ''warning in child lettering,'' which appears on pages 17 and 18 of the document ''Proposed Required Warning Images;'' and ''girl in oxygen mask,'' which appears on pages 19 and 20 of the document ''Proposed Required Warning Images.''

Smoke at toddler. In FDA's research study, the image ''smoke at toddler'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, difficult to look at measure) in all three study populations (adults, young adults, and youth).

However, as discussed in section III.D of this document, the selected image, ''smoke approaching baby,'' also had significant impacts on all the salience measures in all three study populations, and also showed significant impacts on recall and behavioral intentions in some populations.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 93) FDA received a number of comments that supported the use of the image ''smoke at toddler,'' including comments from individuals, a medical organization, public health advocacy groups, academics, and State and local public health agencies. Some of these comments indicated that the image would cause people to reconsider smoking due to the harm it can cause to others, especially a child or a baby.

Three comments noted that the image showed positive impacts in research studies conducted by the submitters. Specifically, in one submitter's study this image had the relatively greatest impact in discouraging respondents from wanting to smoke of the images proposed for use with this warning statement. In another submitter's study of the potential effectiveness of the images, this image received the highest overall rating of the images proposed for use with this warning statement. In addition, it was one of the two highest rated images of the FDA images proposed for use with this warning statement in another submitter's study.

FDA also received several comments that opposed use of the image ''smoke at toddler.'' Multiple comments stated that the image would be perceived as demeaning to smokers by suggesting they blow smoke directly at their children, and one comment cited the image as an unreal portrayal. Another comment expressed concern that the image would prompt denial among smokers, who would interpret the image to mean that their children are not at risk if they do not blow smoke directly at them. One comment said the image does not depict a negative health consequence of smoking, while another comment stated the image was too positive, in that the child looked too happy. Finally, another comment stated that other images tested in FDA's research study for use with this warning statement elicited higher scores on the emotional and cognitive reaction scales than this image.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''smoke approaching baby'' for the reasons given in section III.D of this document.

Smoke at baby. In FDA's research study, the image ''smoke at baby'' had significant effects on the emotional and cognitive reaction scales in all three study populations (adults, young adults, and youth) and significant effects on the difficult to look at measure in adults and youth. It also showed higher correct recall of the warning statement compared to the control in adults and young adults at 1 week follow-up.

However, as discussed in section III.D of this document, the selected image, ''smoke approaching baby,'' had significant impacts on all the salience measures in all three study populations, and also showed significant impacts on recall and behavioral intentions in some populations.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 94) FDA received several comments that supported the use of the image ''smoke at baby,'' including comments from individuals, a community organization, a medical organization, academics, and a State public health agency. Some of these comments indicated that the image would cause people to reconsider smoking due to the harm it can cause to children, and one comment noted that the image evokes a strong emotional reaction, clearly communicating that it is wrong to engage in the behavior portrayed in the image.

Two comments noted that the image showed positive impacts in research

studies conducted by the submitters. Specifically, this image had a significant impact in discouraging respondents from wanting to smoke in one submitter's study, and it was one of the two highest-rated images of the FDA images proposed for use with this warning statement in another submitter's study.

FDA also received several comments that opposed the use of the image ''smoke at baby.'' Many of these comments objected to the graphic illustration style used in the image, with some stating it would be ineffective or less effective than a photographic image, and some indicating it would detract from the seriousness of the message being conveyed. Some comments also expressed concern that the style would inappropriately appeal to youth without deterring them from smoking.

Multiple comments stated that the image would be perceived as demeaning to smokers by suggesting they blow smoke directly at their children, and one comment cited the image as an unreal portrayal. Another comment expressed concern that the image would prompt denial among smokers, who would interpret the image to mean that their children are not at risk if they do not blow smoke directly at them.

A couple of comments stated that other images tested in FDA's research study for use with this warning statement outperformed this image, with one noting that other images elicited higher scores on the emotional reaction scale and difficult to look at measure than this image, and another noting that other images had higher scores on the quit intentions and recall measures than this image.

One comment expressed concern that the image could be perceived to mean that mothers who smoke should not breastfeed their children. Another comment stated that the text used in the proposed required warning was difficult to read.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''smoke approaching baby'' for the reasons given in section III.D of this document.

Girl crying. In FDA's research study, the image ''girl crying'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). It also showed higher correct recall of the warning statement compared to the control in adults at baseline, and higher correct recall of the warning statement at 1 week follow-up compared to the text-only control for adults and young adults. Youth who viewed the image also reported that they would be significantly less likely to be smoking 1 year from now compared to youth who viewed the control.

However, the image had a significant negative impact on adult beliefs about the health risks of secondhand smoke exposure for nonsmokers, *i.e.,* adults who viewed the image were less likely to believe that nonsmokers will suffer from negative health effects due to secondhand smoke exposure than adults who viewed the text-only control.

As discussed in section III.D of this document, the selected image, ''smoke approaching baby,'' had significant impacts on all the salience measures in all three study populations, and also showed significant impacts on recall and behavioral intentions in some populations. Thus, while ''girl crying'' showed positive effects on several important measures in FDA's research study, the selected image was considered to be a stronger choice, as it also showed positive effects on several important measures and did not show any negative effects.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 95) FDA received several comments that supported the use of the image ''girl crying,'' including comments from individuals and from a State public health agency. Some comments noted that the submitter found this image to be the most effective of the images proposed for use with this warning statement, and others noted it would appropriately elicit negative emotions in viewers.

FDA also received several comments that opposed use of the image ''girl crying.'' Multiple comments stated that it was not clear why the girl was crying, and one comment stated that the image does not depict a health consequence of secondhand smoke exposure. One comment indicated that the image was too sensational to be effective, and another comment cited the image as an unreal portrayal, stating that young children do not know they are being harmed when they are exposed to smoke and thus would not cry as a result of such exposure, and noted that this is what makes secondhand smoke exposure so insidious. One comment indicated that other images tested in FDA's research study for use with this warning statement had superior overall results to this image.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''smoke approaching baby'' for the reasons given in section III.D of this document.

Warning in child lettering. In FDA's research study, the image ''warning in child lettering'' had significant effects on the emotional and cognitive reaction scales in all three study populations (adults, young adults, and youth). It also showed higher correct recall of the warning statement compared to the control in adults and young adults at baseline, and higher correct recall of the warning statement at 1 week follow-up compared to the control for adults, young adults, and youth. However, ''warning in child lettering'' showed lower correct recall of the image at baseline and follow-up for adults, young adults, and youth compared to the other images.

Looking across the different measures used in FDA's research study, this image was relatively less effective than other images proposed for use with this warning statement, including the image selected for use in the required warnings, ''smoke approaching baby.''

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 96) FDA received several comments that supported the use of the image ''warning in child lettering,'' including comments from individuals, a public health advocacy group, a medical organization, and a State public health agency. Some comments felt the use of child's handwriting in the image would be especially impactful with parents, and one comment noted that this image would have wide appeal, resonating with parents of any race or ethnicity.

FDA also received several comments that opposed use of the image ''warning in child lettering.'' Multiple comments objected to the image style, indicating that a photographic depiction would be more effective at deterring people from smoking, with one comment noting that the image style would be inappropriately appealing to youth without discouraging them from smoking. One comment indicated that the image does not depict a negative health consequence of smoking, and another indicated that the image was not eye-catching.

Two comments noted that other images proposed for use with this warning statement had superior overall results compared to this image in FDA's research study and stated that FDA should not select this image for use in the required warning. In addition, two comments noted that the image was not highly rated in research studies conducted by the submitters. One comment noted that the image was

ranked as the least effective of the 36 proposed images by respondents in the submitter's study, while another noted that the image was ranked the lowest by a considerable margin of the images proposed for use with this warning statement in the submitter's study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''smoke approaching baby'' for the reasons given in section III.D of this document.

Girl in oxygen mask. In FDA's research study, the image ''girl in oxygen mask'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth).

However, the image had a significant negative impact on adult beliefs about the health risks of secondhand smoke exposure for nonsmokers, *i.e.,* adults who viewed the image were less likely to believe that nonsmokers will suffer from negative health effects due to secondhand smoke exposure than adults who viewed the text-only control.

As discussed in section III.D of this document, the selected image, ''smoke approaching baby,'' had significant impacts on all the salience measures in all three study populations, and also showed significant impacts on recall and behavioral intentions in some populations. Thus, the selected image was considered to be a stronger choice than ''girl in oxygen mask,'' as it showed positive effects on several important measures, but did not show any negative effects.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 97) FDA received a number of comments that supported the use of the image ''girl in oxygen mask,'' including comments from individuals, a public health advocacy group, a medical organization, a health care professional, and a State public health agency, with some comments noting that the image clearly conveys the message that smoke exposure can harm children, and powerfully shows the consequences of smoking.

FDA also received several comments that opposed use of the image ''girl in oxygen mask.'' Some comments noted that it was unclear that the person portrayed in the image was a child, and suggested that the image would be more persuasive if the person shown were younger. One comment expressed concern that persons of low socioeconomic status would not understand the image, and a few comments suggested that the image should show more severe disease or more clear association between the girl's illness and smoke exposure.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''smoke approaching baby'' for the reasons given in section III.D of this document.

3. ''WARNING: Cigarettes Cause Fatal Lung Disease''

As discussed in section III.D of this document, FDA selected the image ''healthy/diseased lungs'' for use with the statement, ''WARNING: Cigarettes cause fatal lung disease.'' FDA proposed three other images for use with this statement: ''toe tag,'' which appears on pages 21 and 22 of the document ''Proposed Required Warning Images;'' ''lungs full of cigarettes,'' which appears on pages 23 and 24 of the document ''Proposed Required Warning Images;'' and ''Dr. [doctor] with X-ray,'' which appears on pages 27 and 28 of the document ''Proposed Required Warning Images.''

Toe tag. In FDA's research study, the image ''toe tag'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth).

However, as discussed in section III.D of this document, the selected image, ''healthy/diseased lungs,'' had the numerically largest effects of the images proposed for use with this warning statement on all the salience measures in all three study populations.

The image ''toe tag'' prompted lower correct recall of the warning statement than the text-only control at baseline among youth.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 98) FDA received a number of comments that supported the use of the image ''toe tag,'' including comments from individuals, a medical organization, public health advocacy groups, academics, and State and local public health agencies. Some of these comments indicated that the image is the best choice for use with this warning statement. It was also noted that the image effectively communicates the risks of smoking and would effectively deter smokers.

Some comments noted that the image showed positive effects in research studies conducted by the submitters. Specifically, this image was rated highly on its ease of comprehension and induced relatively greater worry and led to higher ratings of feeling discouraged from wanting to smoke than a text-only control in one submitter's study. The image was also one of the five images rated most effective among the images used in FDA's 36 proposed required warnings in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''toe tag,'' with some submitters indicating that consumers, and in particular minority populations, might not understand what the image of a toe tag signifies. Some comments stated that the image ''offend[s] against human dignity'' or is ''too sensational to be effective,'' while it was alternatively stated that the image should be more graphic or show more suffering. It was also noted in the comments that the image did not test as well as other images proposed for use with this warning statement in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''healthy/diseased lungs'' for the reasons given in section III.D of this document.

Lungs full of cigarettes. In FDA's research study, the image ''lungs full of cigarettes'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth).

However, as discussed in section III.D of this document, the selected image, ''healthy/diseased lungs,'' had the numerically largest effects of the images proposed for use with this warning statement on all the salience measures in all three study populations.

Among young adults, the image ''lungs full of cigarettes'' prompted higher correct recall of the warning statement at baseline and at 1 week follow-up than the text-only control. The required warning featuring this image also prompted higher correct recall of the image at baseline and follow-up among adults and youth than some of the other images proposed for use with this warning statement.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 99) FDA received some comments that supported the use of the image ''lungs full of cigarettes,'' including comments from individuals and State and local public health agencies. Some of these comments indicated that the image is the best choice for use with this warning statement, while some also noted that

the image is particularly appropriate for use with the warning statement.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. However, the image was rated as one of the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''lungs full of cigarettes,'' with some submitters indicating that consumers might not understand the image, and some comments stating that the image should show the consequences of lung disease on a real person or on real lungs and suggesting that the proposed image did not depict health consequences in an understandable, hard-hitting manner. One comment noted that the secondary message highlighted by the use of bold face emphasis in this proposed required warning (''I cause disease''), could be interpreted as blaming smokers for their addiction, and expressed concern that this could undermine the proposed required warning's ability to communicate effectively with smokers. One comment also stated that the image did not show desirable effects on some measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''healthy/diseased lungs'' for the reasons given in section III.D of this document.

Dr. with X-ray. In FDA's research study, the image ''Dr. [doctor] with X-ray'' had significant effects on the emotional and cognitive reaction scales in all three study populations (adults, young adults, and youth). It also had significant effects on the difficult to look at measure in adults and youth.

As discussed in section III.D of this document, the selected image, ''healthy/diseased lungs,'' had significant effects on all the salience measures in all study populations, and had the largest numerical effects of the images proposed for use with this warning statement on the salience measures.

Among young adults, the image ''Dr. with X-ray'' prompted higher correct recall of the warning statement at baseline and at 1 week follow-up than the text-only control, as well as higher correct recall of the warning statement at follow-up among youth and the adult sample that viewed a hypothetical advertisement featuring this proposed required warning.

However, among young adults, as well as among the adult sample who viewed a hypothetical advertisement featuring this image, ''Dr. with X-ray'' was negatively associated with beliefs about the health risks of secondhand smoke exposure to nonsmokers (*i.e.,* participants viewing this image were less likely to believe that nonsmokers will suffer health consequences related to secondhand smoke exposure than participants viewing the text-only control).

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 100) FDA received some comments that supported the use of the image ''Dr. with X-ray,'' including comments from individuals, a public health advocacy group, a community organization, and a State public health agency. These comments noted that the ''Dr. with X-ray'' image is particularly appropriate for use with the warning statement, or expressed the view that the image is the best choice for use with this warning statement.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed required warnings. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension in one submitter's study, but failed to show an effect on other study measures (worry, discouragement from smoking). The image was one of the five images rated least effective among the images used in FDA's 36 proposed required warnings in another submitter's study of the potential effectiveness of the images, and it was also rated as the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''Dr. with X-ray,'' with some submitters indicating that the X-ray shown in the image is unclear and that the image would not be understood by consumers, and some indicating that it was too vague or clinical in nature and did not effectively convey the full impact of lung disease. It was also noted in the comments that the image failed to show desirable effects on some measures in FDA's research study, and that it showed negative effects on the beliefs measure among some of the study participants.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''healthy/diseased lungs'' for the reasons given in section III.D of this document.

4. ''WARNING: Cigarettes Cause Cancer''

As discussed in section III.D of this document, FDA selected the image ''cancerous lesion on lip'' for use with the statement, ''WARNING: Cigarettes cause cancer.'' FDA proposed three other images for use with this statement: ''Deathly ill woman,'' which appears on pages 29 and 30 of the document ''Proposed Required Warning Images;'' ''white cigarette burning,'' which appears on pages 31 and 32 of the document ''Proposed Required Warning Images;'' and ''red cigarette burning,'' which appears on pages 35 and 36 of the document ''Proposed Required Warning Images.''

Deathly ill woman. The image ''deathly ill woman'' had strong overall research results in FDA's research study, including significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth).

However, overall the selected image, ''cancerous lesion on lip,'' had slightly higher numerical scores on the emotional and cognitive reaction scales than this image.

Among adults, the image ''deathly ill woman'' prompted lower correct recall of the warning statement at baseline and at 1 week follow-up. However, the image showed some of the largest effect sizes for image recall (baseline and follow-up) across the images proposed for use with this warning statement.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 101) FDA received a large number of comments that supported the use of the image ''deathly ill woman,'' including comments from individuals, public health advocacy groups, medical organizations, academics, and State and local public health agencies. Many of these comments indicated that this image is the best image for use with this warning statement, with some stating that the image would communicate effectively to women and other comments approving of the image's accurate portrayal of the effects cancer can have on personal appearance.

Some comments noted that the image showed positive impacts in research studies conducted by the submitters. Specifically, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. The submitter concludes that this image, along with ''cancerous lesion on lip,'' was the most effective of the images proposed for use with this warning statement. The image was also one of the five images rated most effective among the images used in FDA's 36 proposed required warnings in another submitter's study of the potential effectiveness of the images. It was also one of two images rated effective among FDA's 36 proposed color graphic in another submitter's study of the effectiveness of the images at stopping someone from smoking, and it was identified by high school students as one of the ''top three'' proposed required warnings in another submitter's study.

FDA also received comments that opposed the use of the image ''deathly ill woman.'' Some comments noted that the image ''offend[s] against human dignity,'' while one stated it was ''too sensational to be effective.'' Conversely, some comments indicated that the image should show more obvious signs of illness. It was also noted in the comments that the image did not show desirable effects on all the measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''cancerous lesion on lip'' for the reasons given in section III.D of this document.

White cigarette burning. In FDA's research study, the image ''white cigarette burning'' had significant effects on the emotional and cognitive reaction scales in all three study populations (adults, young adults, and youth). It also had significant effects on the difficult to look at measure in adults.

As discussed in section III.D of this document, the selected image, ''cancerous lesion on lip,'' had significant effects on all the salience measures in all study populations, and showed some of the numerically largest effects on these measures of all the images proposed for use with this warning statement.

Among youth, the image ''white cigarette burning'' prompted higher correct recall of the warning statement at baseline than the text-only control.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 102) FDA received some comments that supported the use of the image ''white cigarette burning,'' including comments from individuals and from State and local public health agencies. These comments noted that the ''white cigarette burning'' image is particularly appropriate for use with the warning statement, or expressed the submitter's preference that the image be used with this warning statement.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension in one submitter's study, but failed to show an effect on other study measures (worry, discouragement from smoking). The image was rated as the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''white cigarette burning,'' with some submitters indicating that the image does not depict the negative health consequences of smoking or that the image is not appropriately evocative of cancer, and some noting that the image is unclear and will not be understood by consumers. Some comments also criticized the design of the image, and one stated that the image is not presented in color as required by the Tobacco Control Act. Some comments also noted that this image of a burning cigarette could trigger cravings in smokers. It was also noted in the comments that the image failed to show desirable effects on some measures in FDA's research study. One comment noted that the secondary message highlighted by the use of bold face emphasis in this proposed required warning (''I cause cancer'') could be interpreted as blaming smokers, and expressed concern that this could undermine the proposed required warning's ability to communicate effectively with smokers.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''cancerous lesion on lip'' for the reasons given in section III.D of this document.

Red cigarette burning. In FDA's research study, the image ''red cigarette burning'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth).

However, the selected image, ''cancerous lesion on lip,'' generally had numerically larger effects than this image on the salience measures.

Among adults, young adults, and youth, the image ''red cigarette burning'' prompted lower correct recall of the warning statement at baseline and at 1 week follow-up. The proposed required warning featuring this image also prompted relatively lower recall of the image at baseline and at 1 week follow-up among adults, young adults, and youth than ''cancerous lesion on lip.''

Youth viewing the image ''red cigarette burning'' reported being more likely to be smoking 1 year from now than youth viewing the text-only control.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 103) FDA received some comments that supported the use of the image ''red cigarette burning,'' including comments from individuals, a public health advocacy group, and from State and local public health agencies. These comments noted that the ''red cigarette burning'' image is particularly appropriate for use with the warning statement, or expressed the submitter's preference that the image be used with this warning statement.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. In another submitter's study, particular aspects of the image were evaluated, and the submitter reported that the use of the color red to accentuate the warning content in ''red cigarette burning'' was effective. However, the image was rated as one of the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images, and the image was rated as one of the five least effective images used in FDA's 36 proposed required warnings in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''red cigarette burning,'' with some submitters indicating that the image does not depict the negative health consequences of smoking or that the image is not appropriately evocative of cancer. Some comments also criticized the design of the image, with one stating that it looked like an image from a cigarette advertisement. Some comments also noted that this image of a burning cigarette could trigger cravings in smokers. It was also noted in the comments that the image failed to show desirable effects on some measures in FDA's research study and showed some undesirable effects. Some comments also suggested that other cancers, including bladder cancer, should be added to the cancers listed in the image.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''cancerous lesion on lip'' for the reasons given in section III.D of this document.

5. ''WARNING: Cigarettes Cause Strokes and Heart Disease''

As discussed in section III.D of this document, FDA selected the image ''oxygen mask on man's face'' for use with the statement, ''WARNING: Cigarettes cause strokes and heart disease.'' FDA proposed three other images for use with this statement: ''hand with oxygen mask,'' which appears on pages 37 and 38 of the document ''Proposed Required Warning Images;'' ''red lightning with heart,'' which appears on pages 41 and 42 of the document ''Proposed Required Warning Images;'' and ''man in pain with hand on chest,'' which appears on pages 43 and 44 of the document ''Proposed Required Warning Images.''

Hand with oxygen mask. In FDA's research study, the image ''hand with oxygen mask'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth).

However, the selected image, ''oxygen mask on man's face,'' also had significant effects on all the salience measures, and generally had numerically larger effects than this image on the emotional reaction scale and the difficult to look at measure.

Adults viewing the image ''hand with oxygen mask'' reported being less likely to quit smoking within the next month than adults viewing the text-only control.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 104) FDA received some comments that supported the use of the image ''hand with oxygen mask,'' including comments from individuals, a community organization, and State public health agencies. These comments noted that the ''hand with oxygen mask'' image is the best image for use with the warning statement or stated that the image was appropriate for use with this warning statement.

As discussed in section III.C of this document, some comments submitted to the docket described results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension and induced relatively greater worry and led to higher ratings of feeling discouraged from wanting to smoke than a text-only control in one submitter's study. However, the image was rated as the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''hand with oxygen mask,'' with some submitters indicating that the image is hard to understand or not appropriately compelling. Some comments also stated that the image would be more appropriate for use with a statement about lung-related health consequences (such as COPD). It was also noted in the comments that the image failed to show desirable effects on some measures in FDA's research study and showed some undesirable effects.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''oxygen mask on man's face'' for the reasons given in section III.D of this document.

Red lightning with heart. In FDA's research study, the image ''red lightning with heart'' had significant effects on the emotional and cognitive reaction scales in all three study populations (adults, young adults, and youth). The image also had significant effects on the difficult to look at measure in adults and young adults.

However, the selected image, ''oxygen mask on man's face,'' had significant effects on all the salience measures in all the study populations, and it generally had numerically larger effects than this image on the salience measures.

Among adults, young adults, and youth, the image ''red lightning with heart'' prompted higher correct recall of the warning statement at 1 week follow-up than the text-only control. However, the proposed required warning featuring this image prompted relatively lower recall of the image at baseline and at 1 week follow-up among youth than the selected image, ''oxygen mask on man's face.''

FDA received several comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 105) FDA received a few comments that supported the use of the image ''red lightning with heart,'' including comments from State and local public health agencies, which noted that this image is appropriate for use with the warning statement.

As discussed in section III.C of this document, some comments submitted to the docket described results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension in one submitter's study, but failed to show an effect on other study measures (worry, discouragement from smoking). The image was rated as one of the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''red lightning with heart,'' with some submitters criticizing the design of the image, which was characterized as too conceptual and not easily understandable. Some comments also criticized the illustration style, stating that it does not have the impact a photograph would have, and would not compel or move viewers, and may inappropriately appeal to youth without discouraging them from smoking. It was also noted in the comments that the image failed to show desirable effects on some measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''oxygen mask on man's face'' for the reasons given in section III.D of this document.

Man in pain with hand on chest. In FDA's research study, the image ''man in pain with hand on chest'' had significant effects on the emotional reaction scale in all three study populations (adults, young adults, and youth). The image also had significant effects on the cognitive reaction scale in young adults and youth, as well as in

adults viewing a hypothetical advertisement containing ''man in pain with hand on chest.'' The image also had significant effects on the difficult to look at measure in adults and youth.

However, the selected image, ''oxygen mask on man's face,'' had significant effects on all the salience measures in all the study populations, and had numerically larger effects than this image on the salience measures.

Among youth, the image ''man in pain with hand on chest'' prompted higher correct recall of the warning statement at 1 week follow-up than the text-only control. However, the proposed required warning featuring this image prompted relatively lower recall of the image at baseline among adults than ''oxygen mask on man's face.''

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 106) FDA received several comments that supported the use of the image ''man in pain with hand on chest,'' including comments from individuals, public health advocacy groups, a health care professional, and a State public health agency. Several of these comments indicated that this image is the best choice for use with this warning statement, with some comments noting that the image appropriately shows how painful heart attacks can be.

As discussed in section III.C of this document, some comments submitted to the docket described results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. However, the image was rated as less effective than the selected image, ''oxygen mask on man's face,'' in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''man in pain with hand on chest.'' Some comments indicated that the image looks like a man with a headache or other ailment rather than a man suffering from heart disease or a stroke, and a few comments indicated the man's hand should be closer to his left side (where his heart is). Some comments stated that the image should feature a younger person to drive home the message that heart disease and strokes can affect young smokers as well as older smokers. One comment suggested that the man shown in the image should be replaced with a man of color. It was also stated in the comments that the image failed to show large effects on salience measures or to show desirable effects on other measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''oxygen mask on man's face'' for the reasons given in section III.D of this document.

6. ''WARNING: Smoking During Pregnancy Can Harm Your Baby''

As discussed in section III.D of this document, FDA selected the image ''baby in incubator'' for use with the statement, ''WARNING: Smoking during pregnancy can harm your baby.'' FDA proposed one other image for use with this statement: ''pacifier & ashtray,'' which appears on pages 47 and 48 of the document ''Proposed Required Warning Images.''

Pacifier & ashtray. In FDA's research study, the image ''pacifier & ashtray'' had significant effects on the emotional and cognitive reaction scales in all three study populations (adults, young adults, and youth). The image also had significant effects on the difficult to look at measure in adults and youth.

However, the selected image, ''baby in incubator,'' had significant effects on all the salience measures in all the study populations, and had numerically larger effects than this image on all the salience measures.

Among young adults, the image ''pacifier & ashtray'' prompted higher correct recall of the warning statement at baseline and at 1 week follow-up than the text-only control. However, the proposed required warning featuring this image prompted relatively lower recall of the image at baseline and at 1 week follow-up among adults, young adults, and youth than the selected image, ''baby in incubator.''

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 107) FDA received several comments that supported the use of the image ''pacifier & ashtray,'' including comments from individuals, public health advocacy groups, and State and local public health agencies. In general, these comments indicated that this image is the best choice for use with this warning statement, with some noting that the image is compelling and powerful.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension compared to a text-only control in one submitter's study, but failed to show an effect on other study measures (worry, discouragement from smoking). The image was also rated as the most effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images, but an image used in another country was rated significantly higher than either of FDA's proposed images in this study (however, as discussed in section III.A of this document, at this time FDA does not believe it is necessary or appropriate to use graphic warnings used in other countries in place of the images developed by FDA).

FDA also received several comments that opposed use of the image ''pacifier & ashtray,'' with some submitters criticizing the design of the image, which was characterized as too symbolic and abstract to be understood, and as lacking in emotional impact. Some comments stated that the image does not show a health consequence of smoking, and some indicated the image is not graphic enough. A few comments also noted that the image would be more appropriate for a warning related to post-partum secondhand smoke-related risks, rather than a pregnancy warning, because pacifiers are used post- rather than pre-partum. One comment stated that the background used for the textual warning statement in the image looks unprofessional. It was also stated in the comments that the image failed to show large effects on the salience measures or to show desirable effects on some other measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''baby in incubator'' for the reasons given in section III.D of this document.

7. ''WARNING: Smoking Can Kill You''

As discussed in section III.D of this document, FDA selected the image ''man with chest staples'' for use with the statement, ''WARNING: Smoking can kill you.'' FDA proposed three other images for use with this statement: ''red coffin with body,'' which appears on pages 51 and 52 of the document ''Proposed Required Warning Images;'' ''man in casket,'' which appears on pages 53 and 54 of the document ''Proposed Required Warning Images;'' and ''cigarettes = RIP,'' which appears

on pages 55 and 56 of the document ''Proposed Required Warning Images.''

Red coffin with body. In FDA's research study, the image ''red coffin with body'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in adults and youth. It also had a significant effect on the cognitive reaction scale in young adults.

However, the selected image, ''man with chest staples,'' had a significant effect on all the salience measures in all study populations, and had numerically larger effects than this image on these measures.

Among adults, the image ''red coffin with body'' prompted higher correct recall of the warning statement at baseline than the text-only control.

The image also had a significant impact on beliefs about the health risks of smoking for smokers relative to the text-only control in the adult sample that viewed a hypothetical advertisement containing the proposed required warning.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 108) FDA received several comments that supported the use of the image ''red coffin with body,'' including comments from individuals and a community organization. Several of these comments indicated that this image is the best choice for use with this warning statement, with some approving of the colors used in the image and some noting that the image gets the message across in a straightforward manner.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension compared to a text-only control in one submitter's study, but failed to show an effect on other study measures (worry, discouragement from smoking). The image was rated as one of the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''red coffin with body,'' with some submitters stating that the image is too conceptual and not easily understandable. Several comments stated that the image is not impactful and is unlikely to be effective, with some indicating the image would be more effective if it were a photograph of an actual person. It was also suggested in the comments that the image style may inappropriately appeal to youth without discouraging them from smoking. Some comments noted that the image failed to show desirable effects on some measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''man with chest staples'' for the reasons given in section III.D of this document.

Man in casket. In FDA's research study, the image ''man in casket'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in adults and youth. It also had a significant effect on the cognitive reaction scale in young adults.

However, the selected image, ''man with chest staples,'' had significant effects on all the salience measures, and generally had numerically larger effects than this image on these measures.

Among youth, the image ''man in casket'' prompted higher correct recall of the warning statement at baseline than the text-only control. However, among young adults, the image ''man in casket'' prompted lower correct recall of the warning statement at baseline than the text-only control.

The image also had a significant impact on beliefs about the health risks of smoking for smokers relative to the text-only control in the adult sample that viewed a hypothetical advertisement containing the proposed required warning.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 109) FDA received several comments that supported the use of the image ''man in casket,'' including comments from individuals, a public health advocacy group, and a State public health agency. Several of these comments indicated that this image is the best choice for use with this warning statement, with some noting that the image grabs viewers' attention and clearly depicts death.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. In another submitter's study, particular aspects of the image were evaluated, and the proposed required warning containing the image ''man in casket'' was found to be significantly more effective at discouraging others from smoking than a text-only statement on the side of a cigarette package. However, the image was rated as less effective than the selected image, ''man with chest staples,'' in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''man in casket.'' Multiple comments stated the image looks staged because the man pictured does not look like he is dead or like he suffered from smoking-related disease. It was also suggested in the comments that the image may not be understood by all cultures. The image was also criticized as lacking a clear association to smoking. It was also noted in the comments that the image failed to show desirable effects on some measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''man with chest staples'' for the reasons given in section III.D of this document.

Cigarettes = RIP. In FDA's research study, the image ''cigarettes = RIP'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in adults and youth. It also had a significant effect on the emotional and cognitive reaction scales in young adults.

However, the selected image, ''man with chest staples,'' had significant effects on all the salience measures in all the study populations, and generally had numerically larger effects than this image on these measures.

Among adults, the image ''cigarettes = RIP'' prompted higher correct recall of the warning statement at baseline than the text-only control. However, the proposed required warning featuring this image prompted relatively lower recall of the image at baseline and at 1 week follow-up than the selected image, ''man with chest staples.''

The image had a significant impact on beliefs about the health risks of smoking for smokers relative to the text-only control in the adult sample that viewed a hypothetical advertisement containing the proposed required warning.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 110) FDA received several comments that supported the use of the image ''cigarettes = RIP,'' including comments from individuals and a State public health agency. Several of these comments indicated that this image is the best choice for use with this warning statement, with some noting that the image gets the message across in a straightforward manner, and one stating that the image will get the attention of youth tobacco users.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension compared to a text-only control in one submitter's study, but failed to show an effect on other study measures (worry, discouragement from smoking). The image was rated as the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''cigarettes = RIP,'' with some submitters stating that the image is too conceptual or indirect and lacks impact, and will not be effective in deterring smoking. Several comments expressed concern that consumers, including individuals from various cultures with limited English proficiency and children, might not understand what the shapes of the cigarette package and tombstone represent, or understand the abbreviation (''RIP'') used in the image. Some comments criticized the style of the image, with some characterizing it as low quality and others objecting on the grounds that it downplays the seriousness of the risk being conveyed and may inappropriately appeal to youth without discouraging them from smoking. It was also stated in the comments that the image failed to show large effects on the salience measures or to show desirable effects on some other measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''man with chest staples'' for the reasons given in section III.D of this document.

8. ''WARNING: Tobacco Smoke Causes Fatal Lung Disease in Nonsmokers''

As discussed in section III.D of this document, FDA selected the image ''woman crying'' for use with the statement, ''WARNING: Tobacco smoke causes fatal lung disease.'' FDA proposed four other images for use with this statement: ''graveyard,'' which appears on pages 59 and 60 of the document ''Proposed Required Warning Images;'' ''man smoke at woman,'' which appears on pages 61 and 62 of the document ''Proposed Required Warning Images;'' ''woman smoke at man,'' which appears on pages 63 and 64 of the document ''Proposed Required Warning Images;'' and ''man hands up & smoke,'' which appears on pages 65 and 66 of the document ''Proposed Required Warning Images.''

Graveyard. In FDA's research study, the image ''graveyard'' had significant effects on the emotional reaction scale in all three study populations (adults, young adults, and youth). The image also had significant effects on the cognitive reaction scale in young adults and youth, and on the difficult to look at measure in youth.

However, the selected image, ''woman crying,'' had significant effects on the salience measures in all study populations, and it generally had numerically larger effects than this image on all the salience measures.

Among adults and youth, the image ''graveyard'' prompted lower correct recall of the warning statement at baseline than the text-only control. Among young adults, the image prompted lower correct recall of the warning statement at 1 week follow-up than the text-only control.

The image ''graveyard'' had a significant impact on beliefs about the health risks of smoking for smokers in young adults.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 111) FDA received several comments that supported the use of the image ''graveyard,'' including comments from individuals, a community organization, and a State public health agency. Several of these comments indicated that this image is the best choice for use with this warning statement, with some noting that the image gets the message across in a straightforward manner, and some noting the image could deter people from starting to smoke.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. This image was also rated as the most effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images, although an image used in another country was rated more highly than this image.

FDA also received several comments that opposed use of the image ''graveyard.'' Some comments indicated that the image would not be effective, noting that it is easy to disregard or, alternatively, too sensational to be effective. It was also stated in the comments that the image did not show large impacts on the emotional reaction scale and failed to show desirable effects on some other measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''woman crying'' for the reasons given in section III.D of this document.

Man smoke at woman. In FDA's research study, the image ''man smoke at woman'' had significant effects on the emotional and cognitive reaction scales in adults, young adults, and youth. The image also had significant effects on the difficult to look at measure in youth.

However, the selected image, ''woman crying,'' had significant effects on the salience measures in all study populations, and had numerically larger effects than this image on the emotional reaction scale and the difficult to look at measure in all study populations.

The proposed required warning featuring this image prompted relatively lower recall of the image at baseline and at 1 week follow-up than the selected image, ''woman crying.''

The image ''man smoke at woman'' had a significant impact on beliefs about the health risks of smoking for smokers in young adults.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 112) FDA received several comments that supported the use of the image ''man smoke at woman,'' including comments from individuals and State public health agencies. Several of these comments indicated that this image is the best choice for use with this warning statement, with some noting that the image would make smokers think about how their habit may cause others to avoid them. It was also noted that the image effectively shows how innocent bystanders are affected by smokers.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. The submitter also concluded that the image was the most effective of the images proposed for use with this warning statement. However, the image was rated as one of the less effective images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''man smoke at woman.'' Some comments indicated that the image is not realistic, stating that smokers do not blow smoke at their friends. One comment indicated that the image failed to portray an obvious health consequence of secondhand smoke, and multiple comments indicated that the image conveyed a bad message by showing the nonsmoker covering her nose and mouth, stating that these actions do not protect you from secondhand smoke. It was also noted in the comments that the image failed to show desirable effects on some measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''woman crying'' for the reasons given in section III.D of this document.

Woman smoke at man. In FDA's research study, the image ''woman smoke at man'' had significant effects on the emotional reaction scale in adults, young adults, and youth. The image also had significant effects on the cognitive reaction scale in young adults and youth, and on the difficult to look at measure in adults and youth.

However, the selected image, ''woman crying,'' had significant effects on the salience measures in all study populations, and it had numerically larger effects than this image on the emotional reaction scale and the difficult to look at measure in all study populations.

Among adults, the image ''woman smoke at man'' prompted higher correct recall of the warning statement at 1 week follow-up than the text-only control. However, among young adults, the image prompted lower correct recall of the warning statement at baseline than the text-only control. The proposed required warning featuring this image also prompted relatively lower recall of the image at baseline and at 1 week follow-up than the selected image, ''woman crying.''

The image ''woman smoke at man'' had a significant impact on young adult's intentions to quit smoking in the next month compared to the text-only control.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 113) FDA received several comments that supported the use of the image ''woman smoke at man,'' including comments from individuals, a public health advocacy group, a medical organization, and State and local public health agencies. Several of these comments indicated that this image is the best choice for use with this warning statement, with some noting that the image will make smokers think about how their actions negatively affect social situations.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension compared to a text-only control in one submitter's study but failed to show an effect on other study measures (worry, discouragement from smoking). The image was rated as one of the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''woman smoke at man.'' Some comments indicated that the image would not be effective, suggesting that it is not impactful and probably would not stop people from smoking. One comment indicated that the image fails to portray an obvious health consequence of secondhand smoke, and another was critical of the actions of the nonsmoker in the image, noting that covering your nose and mouth does not protect you from secondhand smoke. It was also stated in the comments that the image failed to show desirable effects on some measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''woman crying'' for the reasons given in section III.D of this document.

Man hands up & smoke. In FDA's research study, the image ''man hands up & smoke'' had significant effects on the emotional reaction scale in all study populations (adults, young adults, and youth) and on the cognitive reaction scale in young adults and youth.

However, the selected image, ''woman crying,'' had significant effects on all the salience measures in all study populations, and it had numerically larger effects than this image on all these measures.

The proposed required warning featuring the image ''man hands up & smoke'' also prompted relatively lower correct recall of the image at baseline and at 1 week follow-up than the selected image, ''woman crying.''

FDA received several comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 114) FDA received some comments that supported the use of the image ''man hands up & smoke,'' including comments from individuals and a State public health agency. These comments generally indicated that this image would be the best choice for use with this warning statement.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension compared to a text-only control in one submitter's study, but it failed to show an effect on other study measures (worry, discouragement from smoking). The image was rated as the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''man hands up & smoke.'' Some comments indicated that the image is unrealistic in that it looks like the man is in fog or a house fire as opposed to being affected by secondhand smoke. One comment indicated that the image does not portray a health consequence of secondhand smoke; it was also stated in the comments the image is ineffective and unintentionally humorous. One comment stated that the image failed to show large effects on salience measures or to show desirable effects on other measures in FDA's research study and indicated it should not be selected.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''woman crying'' for the reasons given in section III.D of this document.

9. ''WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health''

As discussed in section III.D of this document, FDA selected the image ''man I Quit t-shirt'' for use with the statement, ''WARNING: Quitting smoking now greatly reduces serious risks to your health.'' FDA proposed two other images for use with this statement: ''cigarettes in toilet bowl,'' which appears on pages 69 and 70 of the document ''Proposed Required Warning Images;'' and ''woman blowing bubble,'' which appears on pages 71 and 72 of the document ''Proposed Required Warning Images.''

Cigarettes in toilet bowl. In FDA's research study, the image ''cigarettes in toilet bowl'' had significant effects on the emotional reaction scale in adults and young adults and significant effect on the cognitive reaction scale in all study populations (adults, young adults, and youth).

Among youth, the image ''cigarettes in toilet bowl'' prompted higher correct recall of the warning statement at 1 week follow-up than the text-only control. However, the proposed required warning featuring this image prompted relatively lower recall of the image at baseline and at 1 week follow-up than the selected image, ''man I Quit t-shirt.''

The image ''cigarettes in toilet bowl'' had a significant impact on beliefs about the health risks of smoking for smokers in young adults.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 115) FDA received some comments that supported the use of the image ''cigarettes in toilet bowl,'' including comments from individuals, a community organization, and a local public health agency. Some comments noted that this image is the best choice for use with this warning statement, and it was also noted in the comments that the image is effective because it creates an association between cigarettes and other undesirable things that belong in a toilet bowl.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image failed to show any significant effects in one submitter's study on measures of ease of comprehension, worry, and feeling discouraged from smoking compared to a text-only control. In addition, the image was rated as less effective than the selected image, ''man I Quit t-shirt,'' in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''cigarettes in toilet bowl.'' These comments noted that the image is not clear or does not convey a health consequence of smoking. It was also noted that the image is not easily understood, or alternatively, that it is banal. Multiple comments expressed concern about what is shown in the image, stating that it recommends a bad or unhealthy action (*i.e.,* flushing cigarettes down a toilet, which the comments stated could clog the toilet and pollute the environment). Some comments also stated that the statement was difficult to read in the ''cigarettes in toilet bowl'' image. It was also stated in the comments that the image did not show large effects on the emotional and cognitive reaction scales in FDA's research study and failed to show desirable effects on other measures.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''man I Quit t-shirt'' for the reasons given in section III.D of this document.

Woman blowing bubble. In FDA's research study, the image ''woman blowing bubble'' had a significant effect on the cognitive reaction scale in youth.

The image ''woman blowing bubble'' had a negative impact on youth beliefs about the health risks of smoking for smokers and for nonsmokers (*i.e.,* youth who viewed this image were less likely to believe that smokers will suffer negative health consequences or that nonsmokers exposed to secondhand smoke will suffer negative health consequences than youth who viewed the text-only control). Furthermore, the adult sample that viewed a hypothetical advertisement containing the proposed required warning reported that they were less likely to quit smoking in the next 30 days compared to adults who viewed the text-only control.

(Comment 116) FDA received some comments that supported the use of the image ''woman blowing bubble,'' including comments from individuals, a public health advocacy group, and a State public health agency. Multiple comments noted that the image appropriately shows how quitting smoking allows for a better lung capacity or noted that it effectively conveys the idea that there are beneficial effects of quitting.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image led to lower levels of worry and lower reports of feeling discouraged from smoking relative to a text-only control in one submitter's study. In addition, the image was rated as the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''woman blowing bubble.'' Multiple comments stated that the image is confusing and is not appropriately compelling and would not be effective in encouraging smokers to quit. Some comments indicated that the image does not effectively convey the message contained in the warning statement, and some noted that the image is banal or, alternatively, too positive. Multiple comments also stated the image is hard to understand, and that smokers may not comprehend the association between the image and the warning statement. It was also stated that the image would inappropriately appeal to youth without discouraging them from smoking, and that the image is inappropriate because it is sexually suggestive. It was also noted in the comments that the image showed negative results on some measures in FDA's research study, and failed to show desirable effects on other measures.

(Response) We are not selecting this image for use in a required warning and have instead selected the image ''man I Quit t-shirt'' for the reasons given in section III.D of this document.

10. Image for Advertisements With a Small Surface Area

As discussed in section III.D of this document, FDA selected the image which appears on page 75 of the document entitled ''Proposed Required Warning Images'' for use with the textual warning statements solely in advertisements with a small surface area (defined as less than 12 square inches). We also proposed one other image for use with this statement, which appears on page 74 of the document entitled ''Proposed Required Warning Images.''

The proposed image on page 74 depicts a burning cigarette enclosed by a red circle with a red bar across the image. We did not receive any comments on either of the proposed images.

As explained in section III.D of this document, we have selected the image of a black exclamation mark enclosed within a red equilateral triangle for use

in advertisements with a small surface area because we have concluded that the common purpose of this image, to denote a warning of a threat to health or of a hazard which could result in personal injury, makes it the most appropriate for use in the required warning context.

IV. Comments Regarding Textual Warning Statements

A. Changes to Textual Warning Statements

As we explained in the proposed rule, section 202(b) of the Tobacco Control Act, amending section 4 of FCLAA (15 U.S.C. 1333), gives us the authority to adjust the format, type size, color graphics, and text of any of the required warning statements if such a change ''would promote greater public understanding of the risks associated with the use of tobacco products.'' In addition, under section 4(d) of FCLAA, FDA may adjust the type size, text, and format of the warning statements as the Agency determines appropriate ''so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area.'' Such adjustments, including adjustments to the text and format of some of the warning statements, were included with some of the proposed warnings (75 FR 69524 at 69534). We did not receive comments about these adjustments. Two of the warning statements we have selected for this final rule are presented in all uppercase letters, as they were in the proposal. In addition, one of the proposed required warnings, ''baby in incubator,'' was presented without the signal word ''WARNING.'' The research literature on graphic health warnings indicates that signal words, such as ''Warning,'' have been found to enhance the noticeability of safety warnings and convey the degree of risk (*see* Ref. 40 at p. 33). In the final rule, we are thus not removing the word ''WARNING'' from this required warning, such that the text in this required warning is the same as the text presented in section 201 of the Tobacco Control Act (''WARNING: Smoking during pregnancy can harm your baby'').

Moreover, section 906(d) of the FD&C Act (21 U.S.C. 387f(d)) authorizes FDA to issue regulations restricting the sale or distribution of cigarettes and other tobacco products. As is discussed in more detail in section V.B.6 of this document, a reference to a cessation resource has been included in the final required warnings.

Although we did not receive any comments about the adjustments we made to the text of some of the warning statements in the 36 proposed required warnings, we received numerous comments requesting other changes to the textual statements for the new required warnings, including requests to strengthen the text, to add additional information to the text or to otherwise modify the text of the warnings statements. We also received requests to substitute alternative warning statements for some or all of the textual statements and to expand the warning statements by adding additional statements regarding smoking-related risks. The comments, and our responses, are summarized in the following paragraphs. We also received numerous comments about our proposal to include a reference to a cessation resource in the required warnings; these comments and our responses are summarized in section V.B.6 of this document.

(Comment 117) Several comments suggested that some of the textual warning statements should be changed to include language asserted to be stronger and more direct. For example, multiple comments suggested that the statement, ''WARNING: Tobacco smoke can harm your children,'' should be reworded to be more assertive, for example, to state ''Tobacco smoke harms your children.'' One comment referenced the conclusion from the 2010 Surgeon General's report that there is no risk-free level of exposure to secondhand smoke as support for this modification (Ref. 37). Similarly, multiple comments recommended that FDA change the warning statement, ''WARNING: Smoking during pregnancy can harm your baby,'' to be more strongly worded. For instance, comments suggested this statement could instead be worded as ''WARNING: Smoking during pregnancy harms your baby'' or ''WARNING: Smoking when pregnant harms your baby'' or ''WARNING: Smoking harms your baby'' or ''WARNING: Smoking harms the fetus and babies.'' Multiple comments also suggested the warning statement ''WARNING: Smoking can kill you'' should not be worded in a conditional manner. One comment suggested that the text could instead state ''Smoking kills.''

Similarly, FDA received a number of comments suggesting other modifications that individuals, public health advocacy groups, health care professionals, community organizations, and other groups believed would augment the nine statements. For example, one comment from a public health advocacy group suggested that the statement ''Cigarettes are addictive'' be modified to state ''Cigarettes are HIGHLY addictive,'' while another comment suggested the statement read ''Cigarettes are addictive and shorten your life.'' Similarly, a comment from a health care professional suggested the warning should state ''Cigarettes are addictive and deadly.'' Another comment from a nonprofit foundation suggested that the statement ''Cigarettes cause strokes and heart disease'' be modified to state ''Cigarettes cause strokes, heart disease, and amputations.''

(Response) Section 202(b) of the Tobacco Control Act gives FDA the authority to change the textual warning statements if such a change would promote greater public understanding of the health risks associated with smoking. However, at this point, we decline to make the recommended changes. We are adopting the nine textual statements mandated by Congress in section 4(a)(1) of FCLAA. The nine new textual warning statements objectively communicate some of the major health risks associated with smoking in an effective manner. The new textual statements represent a significant improvement over the current set of warnings in that they are specific, unambiguous, and succinctly describe documented outcomes of cigarette use and exposure. We conclude that these nine new statements will effectively convey the major health risks of smoking, which will help discourage nonsmokers from initiating cigarette use, and encourage current smokers to consider cessation, particularly when combined with graphic images depicting the negative health consequences of smoking.

However, we intend to monitor the effects of these required warnings once they are put into use. We will conduct research and keep abreast of scientific developments regarding the efficacy of various required warnings and the types and elements of various warnings that improve efficacy. Such research will help inform us regarding whether to propose changes to the textual warning statements, such as by using stronger or more direct language, in a future rulemaking.

(Comment 118) Many comments recommended that FDA include additional textual information to give further context for the health warnings. For example, comments requested that FDA add information such as research statistics, factual testimonials, or other explanatory text to further enhance the effectiveness of the new required warnings. Several of the comments suggested specific text for particular warning statements; for example, one comment suggested the warning

statement related to addiction be accompanied by the following explanatory text: ''Studies have shown that tobacco can be harder to quit than heroin or cocaine.'' Other comments suggested that the statement ''WARNING: Cigarettes cause cancer'' be modified to add explanatory text about specific cancers caused by cigarettes, including cancers of the mouth, throat, esophagus, lungs, kidney, bladder, pancreas, stomach, cervix, and bone marrow. Another comment suggested that the statement ''Cigarettes cause strokes and heart disease'' be accompanied by explanatory text stating ''Cigarette smoking doubles your chances of strokes and can cause heart attacks'' and that the statement ''Cigarettes cause fatal lung disease'' be accompanied by explanatory text stating that ''Every cigarette you smoke increases your chances of dying from lung disease.'' In addition, the comment suggested that the statement ''Tobacco smoke causes fatal lung disease in nonsmokers'' be accompanied by explanatory text stating ''You're not the only one smoking cigarettes. The smoke is not just inhaled by smokers, it becomes second-hand smoke, which contains more than 50 cancer agents.'' Another comment suggested adding information to the required warnings that state alternatives to smoking, such as exercise and healthy eating.

(Response) We decline to make such changes at this time. As stated previously, the nine new textual warning statements mandated by Congress in section 4(a)(1) of FCLAA objectively communicate some of the major health risks associated with smoking in an effective manner. In addition, research has shown that warning statements that are short and to the point and that are presented in larger fonts sizes are likely to be more effective (Ref. 40 at p. 33). If the additional requested information were added to the required warnings, the resulting warning statements would be longer, and the font size of the warning statements would likely decrease in order for the information to fit within the specified area. This could undercut the effectiveness of the warnings (*see, e.g.,* Ref. 57). If research later indicates that adding such information to the new required warnings will promote a greater understanding of the risks associated with smoking, we will consider making these changes using our authority under section 202(b) of the Tobacco Control Act.

(Comment 119) One comment suggested that the warning statements that reference ''tobacco smoke'' should be modified to instead reference ''cigarette smoke'' to apply more directly to the target audience.

(Response) We disagree that this change is warranted. The statements in section 4(a)(1) of FCLAA, including those that reference ''tobacco smoke,'' are scientifically accurate, and we do not believe that consumers will fail to understand that the warning statements referencing ''tobacco smoke'' apply to the products on which they appear (*i.e.,* cigarettes), which are tobacco products.

(Comment 120) FDA received a number of comments suggesting that some of the negative health effects that are the subject of individual warning statements be replaced with other warnings. For example, one comment from a medical organization suggested that the statement ''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers'' should instead focus on heart attacks, stating that the magnitude of fatal heart disease caused by secondhand smoke exposure is greater than the magnitude of fatal lung disease caused by secondhand smoke exposure. One comment from an individual suggested that FDA use other warnings about the health harms of smoking instead of the warning about addiction.

Another comment suggested that there should be fewer warnings regarding the health risks of secondhand smoke to babies and children and more warnings directed at young teens and pre-teens. One comment stated that the warnings about smoking during pregnancy and about the harms of tobacco smoke to children are only relevant to those who are pregnant or who have children and suggested that these warnings are thus less impactful than the other warning statements.

However, other comments stated that the warnings about the risks of smoking during pregnancy and about the health risks of secondhand smoke to children address important health issues, will help make smokers aware that they are harming innocent people around them, and will help smokers appreciate the severity and magnitude of some of the lesser-known risks of smoking. One comment from an individual noted that secondhand smoke kills an estimated 45,000 nonsmokers who live with smokers from heart disease each year, as well as increasing the risk of SIDS, acute respiratory infections, ear problems, and severe asthma in children, and causing respiratory symptoms and slowing lung growth in children.

(Response) We decline to amend the warning statements as suggested by the comments. As stated previously, the nine textual statements provided by Congress in section 4(a)(1) of FCLAA appropriately communicate important health risks of smoking. Furthermore, we disagree with the suggestion that there should be fewer warnings about the health risks of smoking during pregnancy and of secondhand smoke to children. These warnings comprise two of the nine warning statements, and we agree with the comments indicating that these warnings communicate information about important health issues and will help smokers understand some of the significant health harms caused by cigarettes. In addition, while these warnings may be especially impactful with parents and expectant parents, using a variety of messages, including messages that may particularly impact certain audiences, will strengthen the overall impact of the required warnings (Ref. 40 at pp. 7–8).

Similarly, we disagree with the suggestion that the warning about addiction should be replaced by a warning about other health hazards. As discussed in the preamble to the proposed rule (75 FR 69524 at 69528 through 69529), the magnitude of public health harm caused by cigarettes is inextricably linked to the addictive nature of these products (Ref. 16 at p. 14 and Ref. 3 at p. xi), and many people, particularly adolescents, have a poor understanding of how difficult it is to quit smoking due to the addictive nature of cigarettes (Ref. 3 at p. 91). Thus, we conclude this is an important and appropriate health warning.

(Comment 121) One comment suggested that graphic health warnings on cigarette packages and advertisements should have one broad warning that states: ''Cigarette smoking may cause cancer, death, and other serious life-threatening health hazards.'' Another comment suggested one broad warning that states: ''Smoking Can Kill You.''

(Response) We disagree. We are not aware of any scientific evidence that one broad warning statement would be more effective in communicating the multitude of health risks to smokers and nonsmokers in all age categories than the nine specific textual warnings specified in section 4(a) of FCLAA.

As noted in the proposed rule, evidence shows that warnings about specific health risks, such as cancer, heart disease, and stroke, are more effective than general warnings (75 FR 69524 at 69533 through 69534). Utilizing a single broad statement like the ones proposed in the comments would also fail to communicate important information about the detrimental effects associated with secondhand smoke—and messages about secondhand smoke have been effective in moving smokers to consider

the health risks associating with smoking (75 FR 69524 at 69534). For example, the new set of warnings includes the following statement: ''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.'' This important warning would be lost if we chose to use just one of the suggested broad warning statements. In addition, one of the new required warnings clearly notifies smokers that if they quit smoking, they can greatly reduce serious risks to their health. Again, that important message would be lost if we were to use just one of the suggested broad statements.

(Comment 122) One comment stated that the ninth warning statement provided by Congress in the Tobacco Control Act, ''WARNING: Quitting smoking now greatly reduces serious risks to your health,'' should appear on all packages after one of the other eight warning statements.

(Response) We disagree that such a change is warranted. As discussed in section V.B.6 of this document, we have included a reference to a cessation resource in the required warnings, which we conclude is more appropriate than including the ninth warning statement in all the required warnings.

(Comment 123) Many comments suggested that FDA add additional warning statements to state that cigarette smoking may increase the risk of other diseases such as bladder cancer, impotence, blindness, or COPD. One comment stated that medical studies have shown that women who smoke a pack of cigarettes a day double the risk of orofacial cleft birth defects in their children, and suggested that a warning be added to include this risk and pictures of children with this birth defect (*citing, e.g.,* Ref. 58). One comment also suggested that the required warnings indicate that smoking may increase the risk of breast cancer. Another comment suggested including messages about short-term effects of smoking, such as nutritional deficiencies.

(Response) We decline to add additional warning statements, as suggested in these comments. At this point, we have determined the nine textual statements mandated by Congress in section 4(a)(1) of FCLAA appropriately communicate major health risks of smoking. As stated previously, we intend to monitor the effects of these required warnings once they are put into use. We will conduct research and keep abreast of scientific developments regarding the efficacy of various required warnings and the types and elements of various warnings that improve efficacy. We intend to use the results of our monitoring and such research to determine whether changes should be made to the nine textual statements in a future rulemaking. We recognize that cigarettes cause negative health consequences in both smokers and nonsmokers beyond those addressed in the nine warning statements provided by Congress, and will take this into account in making future determinations as to whether the textual statements should be revised by rulemaking.

(Comment 124) A few comments also suggested that when FDA initiates a new rulemaking to establish its next set of graphic warnings, the Agency should consider adding health warnings that refer to other smoking-related diseases that are not specifically mentioned in this first set of required warnings.

(Response) We intend to periodically review the required warnings to assess their effectiveness and determine whether the warnings are suffering from wear out. During this review, we intend to examine the scientific literature and possibly conduct our own research to determine if additional textual warnings about the scientifically documented negative health consequences of smoking are appropriate.

(Comment 125) One comment suggested that FDA utilize different warnings with featured messages targeted to specific audiences based on their different attitudes and beliefs. As an example, this comment pointed to the Canadian health warning directed at young males, which stresses that tobacco can make the smoker impotent (Ref. 55).

(Response) We conclude that the nine textual statements required by Congress in section 4(a)(1) of FCLAA are appropriate. In addition, we have selected color graphics to accompany the new warning statements that use a variety of different fonts, typography, and layouts; depict a variety of human subjects; and use a variety of styles, including photographic and graphic illustrations. The required warnings will reach a wide variety of audiences including youth, young adult, and adult smokers and nonsmokers. For information on FDA's selection of images, see section III of this document.

As previously stated, we intend to monitor the effects of these required warnings once they are put into use. If our monitoring finds that the messages are not reaching an appropriately broad population and that targeted messages would be more effective, we will consider revising the textual statements in a future rulemaking.

(Comment 126) One comment suggested that FDA require a standard pack size and shape, which would help to ensure the readability of warnings.

(Response) We do not believe it is necessary to adopt a standard pack size and shape. We have taken steps to ensure that the required warnings will be conspicuous and legible on cigarette packages and in advertisements.

B. Attribution to the Surgeon General

Section 4(a)(1) of FCLAA contains the nine new textual warning statements that, when combined with a graphic image, comprise the required warning. Congress did not include an attribution to the Surgeon General in the new textual warning statements, as it has done in past laws on cigarette health warnings. Accordingly, when we issued our proposed rule and released the 36 proposed required warnings, the textual warning statements did not include a reference to the Surgeon General. A number of comments, including those from former Surgeons General and Commissioned Public Health Service Officers, questioned why the new health warnings no longer contain any attribution to the ''Surgeon General.'' A summary of the comments and our response regarding this issue is included in the following paragraphs.

(Comment 127) The comments noted that, since Surgeon General Luther Terry's 1964 report highlighting the adverse health effects of tobacco use, the Office of the Surgeon General has been inextricably linked to smoking prevention and that the reduction in smoking rates since the initial report and the advent of the first Surgeon General's warning is due to the public confidence associated with the Surgeon General's recommendations. In addition, they claimed that the new warnings would be less effective without the Surgeon General attribution. Two other comments also suggested that FDA include ''the federal government logo'' on the health warnings to communicate that the Department of Health and Human Services (HHS) endorses the health message. Another comment from a public health advocacy group suggested that the warning statements add a reference to FDA and/or the U.S. Government to legitimize the warnings. In contrast, one comment stated that it did not support continued use of the Surgeon General attribution, but if FDA decides to include the attribution, it should be placed on the side of the package where it does not detract from the new health warnings.

(Response) We agree with comments highlighting the benefits of the Surgeon General's work in the area of smoking prevention, but we decline to add the ''Surgeon General'' attribution to the

required warnings at this time. Congress did not include an attribution to the Surgeon General as it has done in the past. In addition, there is inconsistency among the limited scientific literature as to whether the attribution of health warnings to government sources enhances their credibility (*see, e.g.,* Refs. 42, 36, 57, and 59). Attribution to a government resource may increase believability of the information; however, if the government is generally disliked or mistrusted, a government source attribution may result in rejection of the health warning (Ref. 11).

One 1997 study found that the attribution to a government source, including the U.S. Surgeon General, did increase the credibility and viewers' intentions to comply with the warnings for cigarettes (Ref. 57). Similarly, in a study conducted prior to Israel's decision to require new cigarette warnings on packages, researchers found that consumers preferred warnings with attribution to a government source or medical research rather than warnings without attribution (Ref. 59).

However, in a developmental study assessing appropriate attributes for new cigarette warnings in Australia, researchers found that the mention of ''government'' in an attribution reminded smokers that the government collects tax revenue from cigarettes and led smokers to challenge the sincerity of the government in issuing cigarette health warnings (Ref. 48). Similarly, researchers for the European Commission in the European Union looked at respondents' reactions to three potential attributions for cigarette warnings: (1) Government/regulatory bodies; (2) health authorities/cancer charities; and (3) tobacco industry (Ref. 42). They found smokers did not respond well to regulatory bodies as a potential source for cigarette warning messages, believing that government bodies did not care about their smoking behavior or were motivated by self-interest (*Id.*).

Moreover, even though the 1997 study did find benefits associated with government source attribution, researchers also noted the potential trade-offs associated with government attribution (Ref. 57). They noted the surface area restrictions associated with warnings and that the amount of information that one can give without losing readers is limited (*Id.*). They also noted that the addition of attribution information may require the use of smaller font size, which may impact legibility and noticeability of the warning (*Id.*). In fact, as we noted in the preamble to the proposed rule, the length and font size of the existing warnings contribute to their ineffectiveness, and larger font sizes enhance the noticeability of cigarette warnings (75 FR 69524 at 69530 and 69534; Ref. 40 at 30–31). Therefore, given the inconsistency in the available research and the potential tradeoffs associated with including a government source attribution in the required warnings, we conclude that there is insufficient evidence to support addition of an attribution at this time.

We will continue to work in partnership with other components within HHS to educate consumers about the risks of smoking. FDA and others also will continue to conduct research regarding the efficacy of required warnings. If such research indicates that adding the Surgeon General attribution to the cigarette required warnings will improve their efficacy, we will consider adding a government attribution as part of a future rulemaking to update the warnings.

C. Foreign Language Translations

As we explained in the preamble to the proposed rule, consistent with section 4(b) of FCLAA, proposed § 1141.10(b)(2) would mandate that the textual component of the required warning appear in the English language in cigarette advertisements with two exceptions. First, per proposed § 1141.10(b)(2)(i), if an advertisement appears in a non-English language publication, the textual portion of the required warning would need to appear in the predominant language of the publication. Second, per proposed § 1141.10(b)(2)(ii), if an advertisement is in an English language publication but the advertisement itself is presented in a language other than English, the textual portion of the required warning would need to be presented in the same foreign language principally used in the advertisement. To accommodate the potential need for Spanish language translations of the textual warning statements, we included Spanish translations with the proposed rule. We received several comments regarding foreign language translations in advertisements and one comment requesting the use of foreign language translations on packages. We have summarized and responded to these comments in the following paragraphs.

(Comment 128) One comment indicated that the submitter was pleased to see Spanish translations of the warnings, but asked that FDA continue to work with as many languages as possible.

(Response) We understand the importance of ensuring that the textual portion of the required warnings is translated accurately so that the message is appropriately communicated to foreign language speakers. As indicated in the NPRM, we included Spanish language translations in recognition of the fact that Spanish is the foreign language most commonly used for cigarette advertisements in the United States (75 FR 69524 at 69537 through 69538). We also will work with any advertiser who plans to advertise cigarettes in *any* non-English language publication, or who plans to utilize a non-English advertisement in an English-language publication in accordance with § 1141.10(b)(2)(ii). Specifically, upon request, we will assist advertisers in generating a true and accurate translation of the textual statements for the nine new required warnings for use in advertisements that are subject to § 1141.10(b)(2).

(Comment 129) One comment expressed concerns that foreign language translations sometimes can be ''too literal'' and could inappropriately impact the meaning of the warning statement.

(Response) We are sensitive to this concern, and the final rule requires that any translation of the required warning statements results in a true and accurate foreign language version of the warning statements. As stated in the previous response, we will assist any advertiser who plans to advertise cigarettes with a foreign language translation of the required warnings.

(Comment 130) One comment stated that all cigarette advertisements in predominantly Spanish speaking areas, such as Puerto Rico, and in Spanish language publications should include warnings in Spanish. Another comment recommended that the required warnings in advertisements be in the language of the publication or advertisement.

(Response) We agree in certain circumstances. As stated in the proposed rule and required in § 1141.10(b)(2), any advertisement that appears in a Spanish language publication must present the textual portion of the required warning in Spanish (*see* § 1141.10(b)(2)(i)). In addition, for advertisements in English language publications, if the advertisement itself is presented in Spanish, the required warning in the advertisement also must be in Spanish (*see* § 1141.10(b)(2)(ii)). However, if an English language publication that includes English language advertisements is sold in predominantly Spanish speaking areas, the textual component of the required warnings will still be required to appear in

English, as specified by section 4 of FCLAA.

We conclude that these requirements will appropriately ensure that the target audience of any advertisement is able to read and understand both the promotional content of the advertisement and the important warning information.

(Comment 131) One comment requested that the required warnings on all cigarette packages exported to Puerto Rico and Latin America be in Spanish.

(Response) We decline to adopt this request. Section 4(b)(2) of FCLAA and § 1141.10(b)(2) require translation of required warnings for certain advertisements only. Neither FCLAA nor the Tobacco Control Act requires foreign language warnings on cigarette packages sold or distributed within the United States, including within the Commonwealth of Puerto Rico. Furthermore, with limited exceptions, FCLAA does not apply to packages of cigarettes for export from the United States.

V. Description of the Final Rule

A. Overview of the Final Rule

This final rule adds new part 1141 to Title 21 of the Code of Federal Regulations, requiring new warnings on cigarette packages and in cigarette advertisements. These new required warnings consist of the nine textual warning statements set forth in section 201 of the Tobacco Control Act accompanied by color graphic images depicting the negative health consequences of smoking. We have selected nine images, such that each required warning consists of one of the nine textual warning statements and an accompanying color graphic.

As required by section 201 of the Tobacco Control Act, the rule requires the new warnings to appear prominently on cigarette packages and in advertisements, occupying at least 50 percent of the area of the front and rear panels of cigarette packages and the top 20 percent of the area of advertisements. We also have exercised our authority under sections 201 and 202 of the Tobacco Control Act, which allow FDA to adjust the type size, text, and format of the textual warning statements. For example, under section 4(d) of FCLAA (as amended by section 201 of the Tobacco Control Act), FDA may adjust the type size, text, and format as we determine appropriate so that both the textual warning statements and the accompanying graphics are clear, conspicuous, legible, and appear within the specified area. Such adjustments, including adjustments to the type size and the addition of information regarding a cessation resource, are included for the required warnings in this final rule. In addition, we are requiring a reference to 1–800–QUIT–NOW as part of the required warnings in accordance with section 906(d) of the FD&C Act as appropriate for the protection of the public health.

B. Description of Final Regulations and Responses to Comments

1. Section 1141.1—Scope

In the proposed rule, proposed § 1141.1 set forth the scope of the proposed regulations. In particular, proposed § 1141.1(b) limited the applicability of the proposed requirements by clarifying that they would not apply to manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution in the United States. Proposed § 1141(c) described situations where a cigarette retailer would not be in violation of the proposed rule for displaying or selling cigarette packages that do not comply with the rule, so long as certain conditions were met (75 FR 69524 at 69535). We received several comments regarding the scope of the regulation, which we have summarized and responded to in the following paragraphs.

(Comment 132) One comment requested that all imported cigarettes and tobacco products have required warnings to come into U.S. ports and be sold in the United States and its territories, including Puerto Rico.

(Response) We agree that imported cigarette packages must bear a required warning in accordance with section 4 of FCLAA and part 1141. Section 1141.10 provides that it is unlawful for any person to import for sale or distribution within the United States any cigarettes the package of which fails to bear one of the required warnings on both the front and rear panels. Section 1141.3 defines United States to include specified U.S. territories, including Puerto Rico. In addition, as explained in section V.B.2 of this document, we are revising the definition of importer to clarify that the term importer includes any person who imports any cigarette, regardless of where it was manufactured. With respect to whether other tobacco products should have required warnings, we have determined that issue is outside the scope of this rulemaking.

(Comment 133) One comment supported the imposition of the required warnings on all cigarette packages manufactured in the United States, including all exported cigarette packages. The comment said that it would be unconscionable for FDA to protect residents in the United States and not the rest of the world when they are smoking U.S.-made products. According to this comment, cigarettes that are being exported are essentially bought in the United States and these products are under the FDA's jurisdiction.

(Response) We disagree that it is appropriate to impose a requirement that cigarettes that are manufactured in the United States for export bear a required warning. Section 4(a) of FCLAA applies to cigarettes packages that are ''for sale or distribution within the United States.'' Section 12 of FCLAA provides:

> Packages of cigarettes manufactured, imported, or packaged (1) for export from the Unites States or (2) for delivery to a vessel or aircraft, as supplies, for consumption beyond the jurisdiction of the internal revenue laws of the Untied States shall be exempt from the requirements of this Act, but such exemptions shall not apply to cigarettes manufactured, imported, or packaged for sale or distribution to members or units of the Armed Forces of the United States located outside of the United States.

(15 U.S.C. 1340). In addition, many other countries impose their own warning requirements on cigarette packages sold in those countries.

(Comment 134) One comment requested that FDA exercise enforcement discretion for retailers and distributors selling cigarettes that do not bear a specified warning label because retailers do not control the labeling of the products supplied by manufacturers. The comment claimed that if a product is provided by a licensed supplier, and not altered by the distributor, the distributor should likewise be relieved of liability.

(Response) FCLAA provides a very limited exemption for retailers and we do not agree that it is appropriate to broaden the exemption to distributors. Nor do we agree that it is appropriate to adopt a broad enforcement discretion policy for retailers and distributors. By choosing to distribute and sell cigarettes, distributors are under an obligation to make sure that the products they receive from manufacturers, importers, and other distributors and subsequently distribute or sell comply with the law, including checking to see whether the packages include a required warning on the front and rear panel. Retailers, however, are not in violation if they display or sell a cigarette package that includes a health warning, even if it is not one of the nine required warnings, as long as other

statutory requirements are met (*see* 15 U.S.C. 1333(a)(4)). The preamble to the proposed rule made clear that manufacturers, importers, and distributors have the primary responsibility for ensuring that the required warnings on cigarette packages comply with all the provisions of part 1141.

(Comment 135) One comment expressed concern regarding the exemption of retailers from an obligation to ensure packages depict required warnings. This comment claimed that the exemption hampers enforcement, because an inspector needs to be able to seize noncompliant packaging at retail.

(Response) We decline to revise the language of proposed § 1141.1(c). As we explained in the preamble to the proposed rule, the limited retailer exemption is in accordance with section 4(a)(4) of FCLAA. The exemption for retailers is limited to situations where the cigarette package contains a health warning, is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor, and is not altered by the retailer in a way that is material to the requirements of section 4(a) of FCLAA. We note, however, that § 1141.1(c) describes situations where a retailer is not considered in violation of part 1141; this exemption does not apply to manufacturers, importers, or distributors that provide retailers with noncompliant cigarette packages. Thus, although a retailer would not be held liable for selling or offering for sale a cigarette package that is not in full compliance with the requirements of part 1141, so long as the retailer fits within the exemption set forth in § 1141.1(c), the manufacturer, importer, or distributor that provided the noncompliant packages would be liable for violating FCLAA and these regulations. Furthermore, the misbranding provisions in § 1141.14 apply to the cigarettes themselves. Therefore, if we discover misbranded cigarette packages in a retail establishment, but the retailer fits within the exemption set forth in § 1141.1(c), we could still initiate a seizure action under section 304 of the FD&C Act (21 U.S.C. 334).

(Comment 136) One comment requested that FDA revise its 2010 Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (75 FR 13225, March 19, 2010) (''reissued 1996 rule'') to ensure that the Agency does not exceed the scope of the Tobacco Control Act by imposing liability on retailers and distributors for labeling or advertising in specific situations. This comment contended that the Tobacco Control Act provides specific situations in which retailers should not be held liable for labeling or advertising and those situations are not recognized in the reissued 1996 rule.

(Response) Section 201 of the Tobacco Control Act, amending section 4 of FCLAA to require graphic warnings, does contain a specific exemption for retailers in certain circumstances, and proposed § 1141.1(c) and (d) recognized this exemption. Section 102 of the Tobacco Control Act required FDA to reissue the 1996 Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (61 FR 44396, August 28, 1996) with certain specified exceptions. We have complied with this requirement (75 FR 13225). However, section 102 of the Tobacco Control Act did not specify that the reissued 1996 rule contain an exemption for retailers or distributors. Consequently, this graphic warning rulemaking did not propose any revisions to the reissued 1996 rule (currently codified at 21 CFR part 1140).

(Comment 137) Multiple comments advocated for the placement of graphic warnings on all tobacco products, including smokeless tobacco products.

(Response) We decline to require warnings on other tobacco products in this rulemaking. In section 4(d) of FCLAA, Congress directed FDA to issue regulations to require color graphic images to accompany the warnings statements required by section 4(a)(1) of FCLAA. This section of FCLAA requires that the statements be included on cigarette advertisements and cigarette packages. While we may be able to require warnings on other tobacco products under other authority, such action is outside the scope of this rulemaking.

2. Section 1141.3—Definitions

Proposed § 1141.3 included definitions for the following terms:

- Cigarette
- Commerce
- Distributor
- Front panel and rear panel
- Importer
- Manufacturer
- Package
- Person
- Required warning
- Retailer
- United States

We received only a few comments regarding definitions described in the proposed rule. In light of these comments, we are revising the definition of ''importer.''

As explained in the preamble to the proposed rule, proposed § 1141.3 defined ''importer,'' for purposes of part 1141, as any person who introduces into commerce any cigarette that: (1) Was not manufactured in the United States and (2) is intended for sale or distribution to consumers in the United States. Proposed § 1141.3 defined ''retailer'' as any person who sells cigarettes to individuals for personal consumption, or who operates a facility where vending machines or self-service displays of cigarettes are permitted (75 FR 69524 at 69536).

(Comment 138) One comment asked that FDA expand the definition of importer to include persons who introduce into commerce cigarettes manufactured in the United States, exported from the United States, and subsequently imported. According to this comment, legislation in 2000 substantially curtailed this practice, but it is still possible.

(Response) We agree that any person who introduces into commerce cigarettes that were imported into the United States, regardless of where those cigarettes were manufactured, should be considered an importer. We are revising the definition of importer to clarify this point.

(Comment 139) With respect to the definition of retailer, one comment requested that FDA revise the definition to clarify that Internet sellers are included in this definition. The comment noted that it appears the retailer definition is broad enough to cover Internet sellers, but clarification would avoid any arguments to the contrary.

(Response) We have determined that revisions to the definition of retailer are not needed. The definition is clear that any person, including an Internet seller, who sells cigarettes to individuals for personal consumption is a retailer. The comment provided no examples of possible arguments for why an Internet seller would not meet the definition of retailer and provided no alternate language for the definition. It may be possible that an Internet seller would not be considered a retailer because it is not selling cigarettes to individuals for personal consumption. In that case, however, the Internet seller would likely meet the definition of distributor and, if so, would be responsible for complying with all responsibilities of distributors under part 1141 and section 4 of FCLAA.

3. Section 1141.10—Required Warnings

The Tobacco Control Act directs FDA to require that color graphic images depicting the negative health

consequences of smoking accompany each of the textual warning statements that must be randomly displayed on cigarette packages (*i.e.,* in each 12-month period, all of the different warnings must appear in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed) and rotated quarterly in cigarette advertisements under FCLAA. Accordingly, in proposed § 1141.10, we proposed that cigarette packages and advertisements contain such a combination graphic-textual warning.

Proposed § 1141.10 provided that the warnings required by this section be obtained from two documents entitled ''Cigarette Required Warnings—English and Spanish'' and ''Cigarette Required Warnings—Other Foreign Language Advertisements.'' ''Cigarette Required Warnings—English and Spanish'' was proposed to contain the required warnings that must be included on all cigarette packages, and in cigarette advertisements in which the text of the required warning must be set forth in the English language or the Spanish language. ''Cigarette Required Warnings—Other Foreign Language Advertisements'' was proposed to contain the electronic files that were to be used to generate the required warnings for advertisements in which the text of the required warning must be set forth in a foreign language (other than Spanish).

The material that was proposed to be contained in the two documents entitled ''Cigarette Required Warnings—English and Spanish'' and ''Cigarette Required Warnings—Other Foreign Language Advertisements'' is now contained in a single document entitled ''Cigarette Required Warnings.'' We have provided this information in a single document because each of the electronic files for use in advertisements contained in ''Cigarette Required Warnings'' allows users to select an English or Spanish textual warning statement or to remove the textual warning statement and insert a true and accurate foreign language (other than Spanish) translation of the warning statement into the file. It is thus unnecessary to provide separate documents with electronic files for English and Spanish language advertisements and for advertisements in which the text of the required warning must be set forth in a foreign language (other than Spanish). Section 1141.10 has been updated to reference this single document, ''Cigarette Required Warnings,'' rather than the two proposed documents (''Cigarette Required Warnings—English and Spanish'' and ''Cigarette Required Warnings—Other Foreign Language Advertisements'').

Section 1141.10(a) sets forth the requirement specific to cigarette packages, explaining that the new required warning must comprise at least the top 50 percent of the front and rear panels of the package, except for cartons where the warnings shall comprise 50 percent of the left side of the front and rear panels. This regulation implements section 4(a)(2) of FCLAA and is in line with the provisions of the Framework Convention on Tobacco Control (FCTC) (Ref. 60). Section 1141.10(a)(3) specifically provides that the ''required warning shall appear directly on the package and shall be clearly visible underneath the cellophane or other clear wrapping.'' Section 1141.10(b) sets forth the requirements for advertisements, including the requirement that the warnings comprise at least 20 percent of the area of the advertisements. Section 1141.10(c) provides that the required warnings shall be indelibly printed on or permanently affixed to the package or advertisement. For the final rule, we have deleted the language from § 1141.10(a)(2) and (b)(3) that specified that the electronic images must be adapted as necessary to meet the requirements of section 4 of FCLAA and part 1141. As explained in the NPRM (75 FR 69524 at 69536 through 69538), this language was used to indicate that regulated entities should modify the size of the required warnings to ensure they are the required size and occupy the required area of the cigarette package or advertisement. However, § 1141.10(a)(4) and (b)(5) set forth the size and placement requirements for required warnings on packages and advertisements, so this language in proposed § 1141.10(a)(2) and (b)(3) was not necessary. In addition, § 1141.10(a)(1) and (b)(1) make clear that the required warnings on cigarette packages and in cigarette advertisements must be ''in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act.''

We also have made minimal changes to § 1141.10(b)(4), which used similar language. Specifically, proposed § 1141.10(b)(4) indicated that the required warnings for foreign language advertisements (other than Spanish) must be adapted as necessary to meet the requirements of section 4 of FCLAA and part 1141. For clarity, we have modified this language to indicate that the textual warning statement that is inserted into the electronic images must comply with the requirements of section 4(b)(2) of FCLAA. As explained in the NPRM (75 FR 69524 at 69538), proposed § 1141.10(b)(4) would have required regulated entities to obtain color graphics for foreign language required warnings, other than Spanish language warnings, from the electronic files contained in ''Cigarette Required Warnings—Other Foreign Language Advertisements,'' and regulated entities would have to insert a true and accurate foreign language translation of the textual warning required by FCLAA into the electronic file to generate the required warning (as explained previously, these electronic files are now contained in the document entitled ''Cigarette Required Warnings''). While the electronic file obtained from ''Cigarette Required Warnings'' contains some of the elements required by FCLAA (*e.g.,* a rectangular border to enclose the required warnings and the color graphic to accompany the label statement), the textual warning statement that regulated entities insert into the electronic file in accordance with § 1141.10(b)(4) must comply with the requirements of section 4(b)(2) of FCLAA. This section provides, among other things, format specifications related to the textual warning statements in cigarette advertising, including required type sizes and color specifications (*i.e.,* the text of the label statement shall be black if the background is white and white if the background is black), and requires that the statements appear in conspicuous and legible type.

In addition, we wish to clarify our intent regarding whether the same warning statement must appear on both the front and rear panels of an individual cigarette package. We believe that section 4(a)(1) of FCLAA is ambiguous as to whether it mandates the use of the same required warning on both the front and rear panels of an individual cigarette package or allows two different required warnings to be used, one on the front panel and the other on the rear panel. We believe that the latter interpretation is reasonable. It is consistent with Congress' intent that all of the required warnings, each of which conveys somewhat different health information, are required to be displayed in the marketplace at the same time (*see* section 4(c)(1) and (c)(3) of FCLAA). While it is possible that two copies of the same statement on a single package might increase the likelihood of the warning being noticed and remembered, we also note that different statements on a single package could lead to greater consumer exposure as well as delay the wear out of the required warnings. Proposed

§ 1141.10(a)(1), along with the description of this provision in the preamble to the proposed rule (75 FR 69524 at 69536), however, implied that the same required warning must appear on both the front and the back of the package. Therefore, we are revising § 1141.10(a)(1) to state, ''It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import * * * any cigarettes the package of which fails to bear * * * one of the required warnings on the front and the rear panels.''

We received comments regarding the format of required warnings on packages and advertisements, the applicability of the requirements to cigarette cartons, and the need for the warnings to remain clearly visible and permanently affixed to packages. A summary of these comments and our responses is provided in the following paragraphs.

(Comment 140) Many comments, including those from health institutions, nonprofit organizations, academics, and consumers, agreed that the significant enhancements to the cigarette health warnings required by § 1141.10 will make them considerably more noticeable and memorable than warnings that currently appear on cigarette packages and in cigarette advertisements. However, many comments also noted that the FCTC Article 11 Guidelines urge parties to cover as much of the principal display areas as possible and that evidence suggests that warnings larger than 50 percent of the principal display areas may be even more effective (*citing* Ref. 41). The comments noted that researchers also have found that smokers correlate the size of the warning label to the importance of the message—the larger the message, the greater magnitude of the risk (*citing* Ref. 61). Accordingly, these comments requested that FDA consider increasing the size of the graphic warnings such that they occupy more than 50 percent of the front and rear panels of cigarette packages.

(Response) We decline to revise the 50 percent area requirement at this time. We have currently determined that this requirement is sufficient to achieve our goals, and this requirement is consistent with the specification set forth by Congress in section 4(a)(2) of FCLAA.

(Comment 141) A few comments expressed the belief that there was no adequate justification for the amount of space mandated for the new required warnings (*i.e.,* 50 percent of the front and back panels of packages and the top 20 percent of the area of advertisements). One comment noted that Congress enacted the 50 percent requirement without committee testimony or other fact-finding as to whether a smaller-sized warning would be effective. The comments asserted that the current size and placement of the warnings on cigarette packages and advertising have contributed to ''complete awareness levels of the dangers of cigarettes.''

(Response) We disagree. As we stated in the preamble to the proposed rule, our assessment of the literature and our experience as a public health agency supports the requirement that the new warnings comprise the top 50 percent of the area of each of the front and rear panels of cigarette packages and the top 20 percent of the area of cigarette advertisements in the United States (75 FR 69524 at 69533). For example, researchers have found that larger graphic warnings are likely to have the greatest impact and that ''larger (label) size means higher visibility and better ability to compete with other package elements'' (Ref. 40 at p. 30). Smokers are more likely to recall larger warnings, and have been found to correlate the size of the warning with the seriousness of the risk (Ref. 61). One Canadian study found that smokers judged warnings that covered 80 percent of the package to be most effective (Ref. 11). In a New Zealand study gauging responses to different sized graphic health warnings (one sized 50 percent of the front of the pack, and another sized 30 percent of the front of the pack), participants strongly preferred the larger sized warning (Ref. 40 at p. 31). Participants felt that the larger sized warning was more prominent, more likely to stand out from product branding, and that some of the messages on the front of the pack remained visible when the pack was open (*Id.* at p. 30). The 50 percent requirement also is consistent with the FCTC (*i.e.,* the required warnings should occupy 50 percent or more of the principal display areas of packages), which was among the substantial evidence considered by Congress when enacting the Tobacco Control Act (FCTC art. 11.1(b)). ''Congress also informed its warning requirements by looking at the use of a nearly identical warning requirement in Canada.'' *Commonwealth Brands* v. *United States,* 678 F. Supp. 2d 512, 531 (W.D. Ky. 2010), *appeal pending sub nom., Discount Tobacco City & Lottery, Inc.* v. *United States,* Nos. 10–5234 & 10–5235 (6th Cir.).

In addition, as described more fully in section II.C of this document, the existing warnings have not been effective in communicating the health risks of smoking, resulting in significant portions of the population that misunderstand or underestimate the health risks of smoking. The new size and placement requirements are needed to increase the salience of cigarette health warnings, which are now considered ''invisible,'' in order to educate the public about the health risks of smoking, which in turn, can positively impact smoking intentions and behaviors (Ref. 3 at p. 291).

(Comment 142) Some comments suggested that the regulation include a font size requirement.

(Response) We note that the proposal included a requirement related to font size and this is retained in the final rule. The final rule mandates that the required warnings be accurately reproduced from the document incorporated by reference entitled ''Cigarette Required Warnings.'' The required font style and font size already will be included in the options within the downloadable files that allow the user to select English and Spanish language warning statements.

For advertisements in foreign languages other than Spanish, companies must comply with the font size requirements in section 4(b)(2) of FCLAA and any format requirements included in the document incorporated by reference (*see* section V.B.4 of this document). In all situations, the textual statements must be conspicuous and legible as required by section 4 of FCLAA.

(Comment 143) One comment from an industry group took issue with FDA's authority to require the new graphic warnings on cigarette cartons, claiming that Congress' intent was to require the new graphic warnings on individual cigarette packs only, not cartons. The submitter recommended that FDA expressly exempt cartons from this requirement.

(Response) We disagree with this comment. FCLAA defines the term ''package'' to mean a ''pack, box, *carton,* or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.'' (section 3(4) of FCLAA (15 U.S.C. 1332(4)) (emphasis added)). Similarly, section 900(13) of the FD&C Act defines the term ''package'' to mean a ''pack, box, *carton,* or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.'' (21 U.S.C. 387(13) (emphasis added)). Given these definitions, it is clear that when Congress decided to require graphic warnings that occupy 50 percent of the front and back panels of cigarette ''packages,'' it intended for this requirement to apply to both individual

packs and cartons. Therefore, § 1141.10(a)(4) continues to mandate that the required warnings must constitute 50 percent of the left side of the front and rear panels of cigarette cartons.

(Comment 144) One comment recommended that FDA require the nine new textual warning statements, included in section 4(a) of FCLAA, to be displayed in the same manner as the display of the existing warnings, because that format has contributed to the public being fully informed about the health risks of smoking.

(Response) We disagree. First, as explained in section II.C of this document, the public is not adequately informed about the health risks of smoking and frequently underestimates those risks. Second, Congress mandated that the format of the new health warnings change from the small warning on the side panel of the pack, covering only 4 percent of the pack, to health warnings that ''comprise the top 50 percent of the front and rear panels of the package'' and ''at least 20 percent of the area of the advertisement.'' (15 U.S.C. 1333(a)(2) and (b)(2)). This is consistent with the FCTC (FCTC art. 11.1(b)). Therefore, we decline to change the format of the required warnings from that included in the proposed rule.

(Comment 145) One comment suggested that the required warnings on cigarette advertisements cover at least 50 percent of the advertisement's principal surface and match the advertisement's primary language.

(Response) As stated in the preamble to the proposed rule and as required by section 4 of FCLAA, § 1141.10(b)(5) mandates that the required warnings comprise *at least* the top 20 percent of the area of the advertisement. Section 4 of FCLAA also requires that the warning statement appear in conspicuous and legible type. At this time, we conclude these requirements are sufficient to ensure that the required warnings are appropriately clear, conspicuous, and legible by consumers.

Moreover, as stated in the preamble to the proposed rule and as indicated in section IV.C of this document, while the textual portion of the required warning in a cigarette advertisement must generally be in English, if an advertisement is presented in a language other than English, the textual portion of the required warning must be presented in the language principally used in the advertisement (*see* § 1141.10(b)(2)(ii)). Therefore, we have determined that modifications to the codified text are not necessary.

(Comment 146) Proposed § 1141.10(a)(5) provided that the ''required warning shall be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation.'' One comment expressed concern that this provision could be problematic if a manufacturer places the brand name and other information vertically on the front and/or back of the cigarette package. The comment believed that this provision would require the warning, or the text of the warning, to appear sideways on the cigarette package.

(Response) The intent of this provision is to ensure that the textual statement in the required warning and other information on the front and rear panels of the package have the same orientation. As explained in the NPRM, this will in turn ensure that the warnings are noticed and read by consumers that are reading the other information found on the package (75 FR 69524 at 69537). Therefore, in the unusual circumstance where a manufacturer chooses to place its brand name or other information such that viewers do not read along the horizontal axis (*i.e.,* from left to right) to read this information, the manufacturer must place the required warning in the same orientation.

(Comment 147) Two comments suggested that the FDA require health warnings on 100 percent of only the front or the rear panel of the cigarette package.

(Response) We disagree. First, section 4(a)(2) of FCLAA specifically requires that the cigarette health warnings ''comprise the top 50 percent of the front and rear panels of the package.'' Second, Article 11 of the FCTC states that the health warnings ''should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas'' (Ref. 60). FDA's new warnings implement Congress' directive and are consistent with the FCTC.

(Comment 148) A few comments suggested that FDA require health warning statements on cigarette papers and/or filters.

(Response) We decline to require warnings on cigarette papers and/or filters. In section 4(d) of FCLAA, Congress directed FDA to issue regulations to require color graphic images to accompany the warnings statements required by section 4(a)(1) of FCLAA. FCLAA requires that the statements be included on advertisements and cigarette packages, not individual cigarette papers or filters. While we may be able to require warnings on papers or filters under other authority, that is outside the scope of this rulemaking.

(Comment 149) One comment suggested that FDA amend the regulation to prohibit distributors from obscuring any portion of the warning label with revenue stamps.

(Response) As written, the proposed rule would prohibit distributors from obscuring any portion of the required warning with revenue stamps. Cigarette packages must comply with the requirement in § 1141.10(a)(3) that the new required warnings be clearly visible. Moreover, in order for the required warnings to appear conspicuously and legibly as mandated by section 4 of FCLAA, the warnings must not be obscured. Thus, if the placement of revenue stamps by a distributor causes the required warnings to not be clearly visible or legible, the distributor would be in violation of these regulations. Therefore, we do not agree that any revisions to § 1141.10 are necessary.

(Comment 150) One comment suggested that FDA require the use of onserts affixed to cigarette packages in addition to the new required warnings, stating that they would enhance the effectiveness of the new health warnings. Similarly, another comment stated that, in addition to the new required warnings, FDA should require that cigarette packages contain inserts with animated warnings containing supplementary or distinct warning messages to enhance the overall warning impression and further engage individuals.

(Response) A requirement to add onserts or inserts is beyond the scope of this rulemaking and, therefore, we decline to require them here.

(Comment 151) One comment stated that there is no empirical basis for concluding that the nine warning statements required under section 4 of FCLAA should be written in large text on the front and back panels of packages in order to convey the health risk information.

(Response) We disagree with this comment and conclude that there is a sufficient empirical basis for concluding that the warning statements should be in large text that is conspicuous and legible. Research has shown that increasing the salience of warnings increases the likelihood of consumers reading warnings and that the salience of a visual warning can be enhanced by using large, bold print (Ref. 62). In addition, after Australia changed their health warnings to six rotated textual warnings with a cessation resource and additional explanatory text in 1995,

researchers found that the increased text size was the most salient feature (Ref. 63). Furthermore, the IOM Report, which provides a summary of the available research on the efficacy of graphic warnings, found that larger, graphic health warnings (including large text and a large graphic) would promote greater public knowledge of the health risks and would help reduce consumption of tobacco products (Ref. 3). The placement of the large text and graphic image on the front and back panels of cigarette packages is consistent with the FCTC, *i.e.,* that health warnings should occupy 50 percent or more of the principal display areas of packages (FCTC art. 11.1(b)).

(Comment 152) One comment claimed that the format of the new required warnings is inconsistent with FDA's drug warning label regime. For example, the comment stated that even for very severe risks, the drug regulations do not require warning information to appear in large text or to occupy a large portion of the packaging. The comment also noted that, in drug advertising, the FDA requires important risk information to be included in a section of the advertisement entitled ''Brief Summary.''

(Response) We have acknowledged that the warning requirements for cigarettes are, and should be, different than the warnings for other FDA-regulated products. As we explained in the preamble to the proposed rule, ''(1) The warning information for cigarettes is different in its applicability than the warning information for other products, (2) the disclosure requirements for other products have a different purpose than the cigarette warnings, and (3) the mechanisms for exposure to warning information are different for tobacco products than for other products FDA regulates'' (75 FR 69524 at 69539). In contrast to medical products regulated by FDA, there is no population that cigarettes are medically appropriate for, and there is no safe method of using cigarettes; the required warnings for these products thus have an inherently different purpose than medical product warning information. The different warning schemes that apply to tobacco products versus medical products are necessary to most effectively communicate the health risks for tobacco products and for other FDA-regulated products.

(Comment 153) One comment claimed that FDA did not provide an adequate justification for requiring the same health warning messages in multiple media, including print advertisements, point-of-sale displays, cartons, and the front and back of individual cigarette packs. This comment claimed that the publication of health warning messages in multiple media will not foster awareness of the information (because it is already known) or belief in it (because it is already believed).

(Response) We disagree. As explained in section II.D of this document, despite existing warning requirements on packages and in advertisements, consumers lack knowledge of the health risks and underestimate the health risks of smoking. It is critical that the negative health consequences of cigarette smoking, which is the leading cause of preventable death and disease in the United States, be clearly, accurately, and effectively conveyed in *all* advertisements and on *all* cigarette packages sold or distributed in the United States.

This is consistent with the requirements of FCLAA. As explained more fully in response to Comment 143, FCLAA's requirements apply to cigarette packages (including cartons), and to advertisements generally.

Further, with its passage of the Tobacco Control Act, Congress noted the pervasiveness of tobacco advertising and how it impacts use, especially promotions directed to attract youths to tobacco products, and found that comprehensive advertising restrictions will have a positive effect on the smoking rates of young people (section 2(15) and 2(25) of the Tobacco Control Act). Therefore, the requirement that the warnings appear in all advertisements, regardless of the medium used for the advertisement, is also consistent with Congress' intent.

(Comment 154) One comment noted that the Federal government warnings on alcoholic beverages are mandated on packages only, presented in small font, and not required on the prominent faces of containers or packaging. According to the comment, this suggests that Congress believes a configuration like the one for alcoholic beverages also would be sufficient for cigarette warnings, particularly given the more widespread use of alcoholic beverages in this country.

(Response) We disagree. Congress clearly intended for the warnings for cigarettes and alcoholic beverages to be different, as evidenced by the different statutory schemes that govern the warning requirements for cigarettes and alcohol products. For cigarettes, Congress clearly set out the location of the health warnings for cigarette packages and advertisements, the area of the package or advertisement that must be covered by the warnings and the requirements for text and background color of the warnings. In addition, Congress provided specific font size requirements for the cigarette warnings (while also affording FDA the authority to initiate a rulemaking proceeding to adjust the format, type sizes, and certain other aspects of the health warnings under sections 4(b)(4) and (d) of FCLAA and section 202(b) of the Tobacco Control Act. In contrast, Congress' health warning requirements for alcoholic beverages, published at 27 U.S.C. 215, do not set forth area, location, and color requirements with as much specificity.

(Comment 155) One comment from an individual consumer expressed concerns that manufacturers may alter their packaging to subvert § 1141.10(c), which mandates that the required warnings on packages and advertisements must be irremovable or permanent.

(Response) The regulation, as drafted, should address the comment's concern. Section 1141.10(c) of the final rule, which is unchanged from what appeared in the proposed rule, states that the ''required warnings shall be indelibly printed on or permanently affixed to the package or advertisement.'' Therefore, regardless of the type of packaging used by manufacturers, all cigarette packages must contain required warnings that are irremovable or permanently affixed to the cigarette packages.

4. Section 1141.12—Incorporation by Reference of Required Warnings

Proposed § 1141.12 proposed that two documents, ''Cigarette Required Warnings—English and Spanish'' and ''Cigarette Required Warnings—Other Foreign Language Advertisements,'' be incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Draft versions of both documents were made available in the docket with the NPRM.

We did not receive comments regarding the use of the incorporated by reference mechanism provided in 5 U.S.C. 552(a) and 1 CFR part 51 and the proposed codified language, or regarding the two draft documents proposed for incorporation by reference. However, as explained in section V.B.3 of this document, the material that was proposed to be contained in the two documents entitled ''Cigarette Required Warnings—English and Spanish'' and ''Cigarette Required Warnings—Other Foreign Language Advertisements'' is now contained in a single document entitled ''Cigarette Required Warnings.'' As a result, we have made nonsubstantive changes to the language used in § 1141.12 to indicate that we are

incorporating ''Cigarette Required Warnings'' by reference (rather than ''Cigarette Required Warnings—English and Spanish'' and ''Cigarette Required Warnings—Other Foreign Language Advertisements''). In addition, we also have updated the incorporation by reference document to include the final electronic files [5] for the required warnings and to add additional formats and instructions for regulated entities to use to place the required warnings on various sizes of cigarette packages (including cartons) and in different sizes and shapes of advertisements, as is discussed in more detail in section VI of this document.

''Cigarette Required Warnings,'' including the electronic files for all of the required warnings and the instructions for their use, is available from a variety of sources. For example, this material is available on a Web site located at *http://www.fda.gov/cigarettewarningfiles.* In addition, regulated entities can request a copy of ''Cigarette Required Warnings'' by submitting a request to FDA at the following e-mail address—*cigarettewarningfiles@fda.hhs.gov*—or by contacting the Center for Tobacco Products, Food and Drug Administration, Office of Health Communication and Education, ATTN: Cigarette Warning File Requests, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–CTP–1373.

5. Section 1141.14—Misbranding of Cigarettes

Proposed § 1141.14(a) provided that a cigarette shall be deemed to be misbranded unless its labeling and advertising bear one of the required warnings. Under section 903(a)(1) and (a)(7)(A) of the FD&C Act (21 U.S.C. 387c(a)(1) and (a)(7)(A)), a tobacco product, including a cigarette, is deemed misbranded if its labeling or advertising is false or misleading in any particular. Under section 201(n) of the FD&C Act (21 U.S.C. 321(n)), in determining whether something is misleading, it: ''Shall be taken into account * * * not only representations made or suggested * * * but also the extent to which the labeling or advertising fails to reveal facts * * * material with respect to consequences which may result from the use of the article to which the labeling or advertising relates * * * under such conditions of use as are customary or usual.'' As explained in the NPRM (75 FR 69524 at 69539), the required warnings are clearly material with respect to consequences that may result from the use of cigarettes.

Proposed § 1141.14(b) provided that a cigarette advertisement or package will be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the FD&C Act if it bears one of the required warnings. It also proposed that a cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8) of the FD&C Act unless the manufacturer, packer, or distributor includes in all advertisements and packages issued or caused to be issued by the manufacturer, packer, or distributor with respect to the cigarette one of the required warnings. We received two comments on the issue, which we have summarized and responded to in the following paragraphs.

(Comment 156) One comment from a tobacco product manufacturer stated that FDA should replace the word ''labeling'' with the word ''packages'' in § 1141.14(a). The comment indicated that FDA should avoid using the word ''labeling'' because that term has a broader meaning under the FD&C Act than it does under FCLAA, and therefore its use in the regulation could create unnecessary ambiguity. The comment also stated that FCLAA only requires warnings on cigarette packages and advertisements.

(Response) We agree that the requirements for inclusion of health warnings set forth in FCLAA apply to each package (*i.e.,* pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers) and each advertisement of cigarettes. The package warnings required by FCLAA are one part of a product's ''labeling,'' as the term ''labeling'' encompasses the package label. We have revised § 1141.14(a) to replace the word ''labeling'' with the word ''packages'' for clarity. We note, however, that section 903 of the FD&C Act, ''Misbranded Tobacco Products,'' provides other ways that tobacco products can be misbranded that extend to tobacco product labeling as well as package labels and advertising. Therefore, in addition to complying with the requirements of FCLAA and this rule, regulated entities must comply with the requirements of section 903 of the FD&C Act to avoid misbranding their tobacco products.

(Comment 157) One comment from a public health advocacy group stated that clarifying changes should be made to the language in § 1141.14 to ensure the regulation accomplishes its intended purpose. Specifically, the comment stated that cigarettes can be deemed misbranded under the FD&C Act unless they meet a number of criteria, and that not all of the criteria relate to health warning requirements. Thus, a regulated entity could comply with the warning requirements, but its cigarette product could still be deemed misbranded under the FD&C Act if it failed to meet other criteria in section 903 of the FD&C Act. The comment suggested the language in section § 1141.14 should clarify this point.

(Response) We agree that cigarettes can be deemed misbranded under the FD&C Act for a number of reasons. We also agree that, although compliance with the requirements of part 1141 is necessary to comply with certain provisions of section 903 of the FD&C Act, this does not guarantee that a cigarette product satisfies all the provisions of section 903 of the FD&C Act. However, we do not agree that changes to the codified text at § 1141.14 are necessary, as the text does not indicate that cigarettes will not be deemed misbranded for any reason if they include required warnings, but rather that cigarettes will be deemed misbranded if they fail to include required warnings.

6. Section 1141.16—Disclosures Regarding Cessation

Section 1141.16 of the NPRM proposed that one or more of the required warnings include specified information about an appropriate smoking cessation resource. As explained in the NPRM, the goal is to provide a place where smokers and other members of the public can obtain smoking cessation information from staff trained specifically to help smokers quit by delivering current, unbiased, and evidence-based information, advice, and support. The NPRM identified a number of possible alternatives for a cessation resource, including use of an existing or new quitline or Web site.

[5] As described in section VI.A of this document, the final electronic files for the required warnings are built as Encapsulated PostScript (.eps) files, which is a format that is commonly used by professional printers. Because members of the public may not have software that can easily view these files, we are placing in the docket Ref. 64, which is composed of .pdf versions of each of the formats for each of the English and Spanish language required warnings, as well as the instructions contained in ''Cigarette Required Warnings.'' We note, however, that these .pdf files do not have the same functionality as the .eps files. Unlike .pdf files, .eps files have separate layers for text and images and the use of these layers can be manipulated by users. In addition, .pdf files are not included for foreign language advertisement warnings (other than Spanish) because regulated entities are responsible for generating a true and accurate translation of the textual warning statement in the required language for such warnings, and thus the final versions of such warnings are not contained in ''Cigarette Required Warnings.''

Although we did not include a specific cessation resource on the proposed images published with the NPRM, we proposed that the final rule would include one or more required warnings containing a cessation resource. We proposed that the resource must meet specific criteria designed to ensure that the cessation information, advice, and support provided are unbiased and evidence-based.

As explained more fully in the following paragraphs, we have decided, based on our authority in section 906(d) of the FD&C Act, to require that all nine required warnings refer to a cessation resource, and we have included this resource in the nine graphic warnings in ''Cigarette Required Warnings,'' which is incorporated by reference (IBR document) as described in section V.B.4 of this document. This final rule specifies the criteria that will be required of any responsible entity providing services through the chosen cessation resource. The resource we have selected is the existing National Network of Tobacco Cessation Quitlines (Network), which uses the telephone portal 1–800–QUIT–NOW. This telephone portal, provided by the National Cancer Institute (NCI), routes calls to the appropriate State quitline, based on the area code of the caller. The Network includes a designated quitline run by or on behalf of each of the 50 states as well as the District of Columbia, Puerto Rico, and Guam (hereinafter referred to as ''State quitlines'' or ''State-run quitlines'').[6] We conclude that this resource will provide the broadest access for smokers throughout the United States to unbiased, evidence-based cessation information, advice, and support. The Centers for Disease Control and Prevention (CDC) already provides significant support and oversight to these State-run quitlines. Beginning with the effective date of this rule, CDC's cooperative agreements with State health departments will specify that the State quitlines must meet the criteria described in § 1141.16(b) to qualify for cessation funding under the cooperative agreement. HHS will monitor the quitlines for compliance with the criteria, and if it determines that a State quitline does not meet the criteria, it will take appropriate steps to bring the State quitline into compliance. What is appropriate will depend on the circumstances of the particular situation. For example, it might involve CDC working with the State quitline to ensure staff are adequately trained. If warranted, it could also include more serious measures such as CDC working with NCI to re-route calls to another resource. Because the record indicates that quitlines that are members of the Network generally comply with the criteria already, we anticipate that any measures to bring quitlines into compliance will be rare.

a. *Rationale and authority for requiring inclusion of a cessation resource.* The NPRM explained that reducing the number of Americans who smoke by increasing the likelihood that smokers will quit smoking would provide substantial public health benefits by reducing the life-threatening consequences associated with continued cigarette use. The NPRM also cited studies finding that health warnings are more effective if they are combined with cessation-related information. Consequently, FDA proposed requiring information about an appropriate smoking cessation resource under section 906(d) of the FD&C Act as appropriate for the protection of the public health (75 FR 69524 at 69540 through 69541). We received a number of comments regarding our rationale and authority to require a cessation resource on the graphic health warnings, which we summarized and responded to in the following paragraphs.

(Comment 158) A large majority of comments that addressed the issue strongly supported inclusion of a cessation resource on all the required warnings. These include comments from public health advocacy groups, medical organizations, academics, State and local public health agencies, and representatives of quitlines. The comments provided a variety of reasons supporting inclusion of a cessation resource on the required warnings. Many comments asserted that a majority of smokers want to quit, and referring smokers to a smoking cessation resource will help them to quit. Some comments cited statistics regarding the number of smokers who actually attempt to quit—about 40 percent of smokers try to quit in a calendar year—and the very low percentage of smokers who are successful—95 percent of those who try to quit on their own relapse (*citing, e.g.,* Ref. 65 and Ref. 66). One comment from a State public health agency asserted that smokers contemplating quitting are motivated by smoking cessation messages to call a State tobacco quitline.

Many comments argued that including a cessation resource is consistent with the guidelines for implementing Article 11 of the FCTC. One comment also stated that including a cessation resource would be consistent with Article 14 and Article 12 of the FCTC. In addition, numerous comments cited evidence from other countries, particularly Australia, New Zealand, the Netherlands, Brazil, Singapore, and the United Kingdom, where adding a smoking cessation quitline number to cigarette warnings significantly increased calls to the quitline (*citing, e.g.,* Refs. 67, 68, 69, 70, 71, 72, and 73). As one comment noted, these results show, consistent with behavior change theory, that providing a quitline number may be a critical component of the required warning that facilitates behavioral action. According to one comment from an academic institution, an evaluation of the impact of including a supportive cessation message accompanied by quitline numbers and Web-based cessation information in seven European countries (Denmark, France, Iceland, The Netherlands, Norway, Poland, and Sweden) found a significant increase in quitline call volume in all countries except Norway. One comment from a submitter representing quitlines stated that it is feasible for the cigarette industry to include a cessation resource on every package of cigarettes, noting that approximately 20 nations currently require a quitline number on their tobacco packages and advertisements.

Many comments cited statistics that smokers who use evidence-based services of telephone quitlines have a two to three times higher rate of success in quitting than smokers making unassisted quit attempts (*citing, e.g.,* Ref. 66). One comment from a local public health agency asserted that media campaigns and educational efforts, while effective, still do not reach all smokers. According to this comment, after extensive outreach, about 25 percent of smokers in that city had never heard of the quitline being promoted and 25 percent of smokers reported that it is not easy for a person interested in quitting smoking to obtain information about ways to quit.

Several comments noted that the purpose of graphic warnings is to inform smokers about the risks of smoking and motivate smokers to want to quit, but this message will be more effective if there is information in the graphic warnings on how smokers can obtain help quitting. Some comments argued that health warnings should not just inform smokers about the dangers of tobacco use, but also provide assurance that quitting is possible and assistance is available. One comment cited research that shocking, fear-arousing images can be more effective when combined with encouragement or

[6] Calls to 1–800–QUIT–NOW from U.S. territories that do not currently have a quitline (*e.g.,* the U.S. Virgin Islands or American Samoa) are routed to a quitline that is run by NCI.

empowering messages (*citing, e.g.,* Ref. 74). Another comment from an academic institution claimed that when people perceive that there is a strategy for them to take positive action to reduce the threat in a fear message, fear appeals successfully changed health-related attitudes and behaviors (*citing, e.g.,* Refs. 75, 76, 77, and 78). However, if people do not believe they have an effective means of avoiding a threat, they may suppress thoughts about the risk, and, as a result, not process the threat information (*citing, e.g.,* Refs. 79, 80, and 81). As one comment from an academic institution explained, under fear appraisal theory, a fear communication message will cause aversive anxiety, which individuals will try to ameliorate through behaviors that reduce the perceived threat. This comment asserted that the positive effects of a fear message depend upon the existence of an available coping option that is perceived to be potentially effective at reducing the threat. In addition, comments cited research that smokers may be more likely to attempt to quit when they know a quitline is available (Ref. 82).

One comment from a submitter representing a State quitline claimed that health care providers are more likely to address tobacco use in their patients when they know of an effective program to which they can refer their patients, and that adding a cessation resource to the required warnings will dramatically increase awareness of this resource. Several comments from submitters representing State quitlines noted that they receive referrals from clinicians via fax referral services.

One comment from an academic researcher submitted results from a study that tested one of the proposed required warnings included in the proposed rule with and without a cessation resource. This study found that when youth and adult participants were asked to rank order six images tested for use with one of the warning statements, based on which image would be most effective for discouraging smoking, the image with the cessation resource was ranked as the most effective by more study participants than any other image.

(Response) We agree with comments that there is strong support for including a smoking cessation resource on the required warnings. As required by section 906(d) of the FD&C Act, we find that addition of a cessation resource is appropriate for the protection of the public health because of the benefits, and lack of risks, to the population as a whole. This is due, in part, to the increased likelihood that existing smokers will become aware of the cessation resource and, consequently, the increased likelihood that existing smokers who want to quit will be successful. It is also due to the likelihood that the reference to a smoking cessation resource will enhance the effectiveness of the warnings required under FCLAA at conveying information about the risks to health from smoking.

As stated in the comments, the majority of smokers want to quit and about 40 percent of smokers attempt to quit each year. In addition, the warnings required under FCLAA and this regulation convey information and promote greater understanding about the significant health risks associated with smoking, which will likely lead additional smokers to decide that they want to quit smoking to address these risks. Also, as discussed in the comments, the vast majority of those attempts are unsuccessful. By including a cessation resource on required warnings, the many smokers who want to quit will receive information about a resource that has been demonstrated to be effective in helping smokers to quit (*see* section V.B.6.c of this document). Media campaigns are helpful in reaching some smokers who want to quit, and can be used in conjunction with the inclusion of a cessation resource on the required warnings. It is important to ensure that this information reaches a broad number of smokers. Inclusion of a cessation resource on the required warnings is likely to have a broader reach than media campaigns alone. The evidence from one comment is that, even after an extensive media campaign, approximately one quarter of smokers surveyed were not aware of the existence of the quitline or that help was available to obtain information about ways to quit. The cessation information will be there each time a consumer looks at a package of cigarettes or a cigarette advertisement; a pack-a-day smoker potentially would be exposed to the cessation information more than 7,000 times per year. This evidence highlights that cigarette packages are useful communication tools for ensuring that smokers are aware of cessation resources.

Based on experience in other countries, we anticipate that including a reference to a cessation resource as part of the required warnings will increase the utilization of that resource. Many foreign countries have included cessation resources on cigarette package warnings. As described in the comments, these countries have generally experienced a large increase in the number of calls to the quitlines following their appearance on cigarette packages. For example, in the Netherlands, the number of callers to the quitline increased more than threefold after a smoking cessation message (''Ask for help with smoking cessation'') and the national quitline number were included on cigarette packages (Ref. 72). Similarly, in Australia, the number of calls to the quitline nearly doubled, compared with the previous 2 years, following the introduction of new color graphic warnings with a prominent quitline number. The increase in call volume persisted in the following year, although it was about 40 percent lower than in the year in which the graphic warnings were first introduced. Although there was a series of mass media campaign activities that accompanied the new graphic warnings, one study concluded it was very unlikely that the mass media campaign alone explained the observed increase in calls because the introduction of the graphic warnings had an independent effect (Ref. 67). In New Zealand, after the introduction of pictorial warnings with a supportive cessation message and quitline information, the average number of new monthly calls increased and the percentage of first-time callers who reported obtaining the quitline number from tobacco product packaging doubled (Ref. 83). In Brazil, there was a progressive increase in calls to a quitline in the 6 months following the requirement for graphic warnings and the inclusion of a quitline number on cigarette packages. Interviews with people who called the quitline showed that over 92 percent knew about the quitline number because it appeared on cigarette packs (Ref. 73). We also note that Canada has recently proposed including a quitline number on the graphic warnings that will appear on its packages.

Although we are not aware of any studies regarding the inclusion of cessation information on graphic warnings in cigarette advertisements, it seems likely that adding a reference to a cessation resource to cigarette advertisements would have a similar effect as including the reference on cigarette packages.

Inclusion of a cessation resource on the required warnings is also consistent with the advice of the FCTC. Although the United States has not yet ratified the FCTC and therefore is not bound by the treaty, the United States is a signatory and the Guidelines for implementation of the Treaty provide further support for the inclusion of a cessation resource. The Guidelines for implementation of

Article 11 of the FCTC (Packaging and labeling of tobacco products) explain that the provision of advice on cessation and specific sources for cessation help on tobacco packaging, such as a Web site address or a toll-free telephone number, can be important in helping tobacco users to change their behavior, and is expected to increase demand for cessation-related services.

In addition to providing information to increase the likelihood that smokers will become aware of the cessation resource and use it to successfully quit, including a cessation resource will also help to make the required warnings more effective at conveying information about the health risks of smoking. As noted in the NPRM, studies have found that health warnings are more effective when they are combined with cessation-related information (75 FR 69524 at 69541). Risk communication research indicates that messages that arouse fear about the health risks of smoking should be combined with information on concrete steps that can be taken to reduce those risks (Ref. 81 (Messages that arouse fear ''appear to be effective when they depict a significant and relevant threat * * * and when they outline effective responses that appear easy to accomplish * * *.''); *see also* Ref. 55 (explaining the importance of giving smokers who are motivated to quit smoking upon seeing a graphic health warning an immediate way to act on this impulse and access cessation assistance)). In addition, the results from one study conducted by an academic researcher and submitted to the docket also suggest that adding a cessation resource to the required warnings is beneficial. When youth and adult participants were asked to rank order six images (including one image with and without a cessation resource) tested for use with one of the warning statements, based on which image would be most effective for discouraging smoking, the image with the cessation resource was ranked as the most effective by more study participants than any other image.

(Comment 159) Several tobacco industry comments claimed that it was difficult to comment on the issue of a cessation resource, because the proposed rule did not identify the resource FDA proposed to reference or suggest alternative resources from among which FDA would choose. Tobacco industry comments also claimed that the NPRM did not indicate how FDA proposed to reference the resource or integrate it into the proposed warning images. For these reasons, some tobacco industry comments contended that the NPRM did not provide adequate notice for requiring inclusion of a cessation resource, and that FDA should not require a cessation resource without providing an additional opportunity to comment on specific proposed cessation resources.

(Response) We disagree. The Administrative Procedure Act requires that a notice of proposed rulemaking include ''either the terms or substance of the proposed rule or a description of the subjects and issues involved'' (5 U.S.C. 553(b)(3)). Consistent with this requirement, the NPRM provided adequate notice that FDA was considering the inclusion of a cessation resource in the required warnings and the factors it would consider in choosing a specific smoking cessation resource. Proposed § 1141.16 specifically stated that one or more of the required warnings ''shall include a reference to a smoking cessation assistance resource'' (75 FR 69524 at 69564). The preamble to the proposed rule explained the goal ''would be to provide a place where smokers and other members of the public can obtain smoking cessation information from staff trained specifically to help smokers quit by delivering unbiased and evidence-based information, advice, and support'' (75 FR 69524 at 69540). The preamble also explained the range of alternatives available, including use of an existing or new quitline or Web site (75 FR 69524 at 69540; *see Small Refiner Lead Phase-Down Task Force* v. *EPA,* 705 F.2d 506, 549 (DC Cir. 1983) (''Agency notice must describe the range of alternatives being considered with reasonable specificity.'')). In addition, proposed § 1141.16(b) identified specific criteria that any referenced cessation resource would need to meet as well as two additional criteria that the resource would need to meet if the resource was a toll-free telephone number (proposed § 1141.16(d)) and two additional, but different, criteria that the resource would need to meet if it was a Web site (proposed § 1141.16(c)). The NPRM further explained that the reference to a smoking cessation resource was proposed to ''be included as part of one or more of the required warnings and therefore would not appear outside of the areas specified for the required warning'' (75 FR 69524 at 69541). Thus, the ''notice was sufficiently descriptive of the subjects and issues involved so that interested parties [could] offer informed criticism and comments'' (*Air Transport Ass'n of America* v. *Civil Aeronautics Bd.,* 732 F.2d 219, 224 (DC Cir. 1980) (*quoting National Small Shipments Traffic Conference, Inc.* v. *CAB,* 618 F.2d 819, 834 (DC Cir. 1980)) (internal quotations omitted)).

Our choice of a specific smoking cessation resource, 1–800–QUIT–NOW and the State quitlines to which it links, is a logical outgrowth of the proposed rule. We received many comments that discussed whether FDA should use a toll-free telephone number and/or a Web site. We also received a comment advocating that the Agency include information about contacting a physician for help quitting (*see* Comment 170). Numerous comments identified an existing resource (primarily 1–800–QUIT–NOW) as the preferred cessation resource for the required warnings. As discussed in section V.B.6.b of this document, many comments addressed the specific criteria proposed for the cessation resource and several comments provided reasons why 1–800–QUIT–NOW meets the criteria identified in the NPRM. In addition to comments received about whether to include a resource and, if so, what resource, as discussed in section V.B.6.d of this document, the proposed rule was sufficiently detailed for comments to raise issues regarding implementation details, such as the words surrounding the cessation resource.

We are generally adopting the criteria identified in the NPRM, including the criteria specific to a toll-free number. Our changes to the criteria are minor clarifications that were informed by comments. Thus, the requirement that the graphic warnings include a reference to a cessation resource is a logical outgrowth of the proposed rule and further notice and opportunity for comment is not necessary (*Air Transport Ass'n of America,* 732 F.2d at 224 (''An Agency adopting final rules that differ from its proposed rules is required to renotice when the changes are so major that the original notice did not adequately frame the subjects for discussion. * * * The agency need not renotice changes that follow logically from or that reasonably develop the rules it proposed originally'') (*quoting Connecticut Light and Power Co.* v. *NRC,* 673 F.2d 525, 533 (DC Cir. 1982))). An agency is permitted to add specific details to a rule in response to comments even if the proposed rule described the requirement in a more general manner (*Chemical Manufacturers Ass'n* v. *EPA,* 870 F.2d 177, 202 (5th Cir. 1989) (finding that EPA provided adequate notice for final rule appendices, one of which established limits for the discharge of certain metals, even though the appendices were not included in the

proposed rule, because there was adequate notice that the agency was considering establishing limitations ''and this was all the APA demands''); *Trans-Pacific Freight Conference of Japan/Korea* v. *Federal Maritime Comm'n,* 650 F.2d 1235, 1248–49 (DC Cir. 1980) (finding that the final rule merely enumerates more specifically the type of information which the Commission sought, but parties were on notice that a requirement of more detailed reports was under consideration)).

b. *Criteria for cessation resource.* The NPRM included three paragraphs in proposed § 1141.16 detailing criteria that would apply, on an ongoing basis, to any cessation resource chosen in the final rule. The purpose of these proposed criteria was to ensure that the cessation information, advice, and support provided by the cessation resource are unbiased and evidence based (75 FR 69524 at 69540). Proposed § 1141.16(b) described 10 criteria that would be applied to any cessation resource chosen. Proposed § 1141.16(c) described two additional criteria that would apply if the cessation resource chosen were a Web site, and proposed § 1141.16(d) described two additional criteria that would apply if the cessation resource chosen were a toll-free telephone number. In addition, the preamble to the proposed rule provided examples and additional explanation to help clarify the proposed criteria (75 FR 69524 at 69540).

As discussed more fully in section V.B.6.c of this document, we have decided that the appropriate cessation resource is a toll-free telephone number (1–800–QUIT–NOW). Therefore, our final rule does not include the criteria proposed for a cessation resource that is a Web site. We have incorporated the two criteria proposed for a cessation resource that is a toll-free telephone number into § 1141.16(b) as paragraphs 11 and 12, deleted the proposed criteria for a Web site, and added a paragraph clarifying an issue raised in the comments.

In the following paragraphs, we summarize and respond to comments regarding our general criteria for a cessation resource, as well as criteria relating to a cessation resource that is a telephone quitline. However, because we are not choosing a Web site as the cessation resource, we do not respond to specific suggestions regarding the criteria in proposed § 1141.16(c) and other comments about criteria for a cessation resource that is a Web site.

(Comment 160) One comment suggested that the rule does not need to specify criteria for the cessation resource. Instead, this comment proposed that FDA rely on the most recent version of the Public Health Service Guideline on Treating Tobacco Use and Dependence (2008 PHS Guideline) (Ref. 66). The rationale for this suggestion was that this guideline is regularly updated to reflect new effective treatments for tobacco dependence and, therefore, the criteria would not become out-of-date. In addition, the comment asserted that the 2008 PHS Guideline is the gold standard for tobacco cessation in the United States, because it is produced by leading cessation experts, updated on a regular basis, and published by HHS.

(Response) We agree with the comment that the 2008 PHS Guideline is a valuable resource for evidence-based smoking cessation treatments. However, the purpose of FDA's criteria is not to reference particular treatment strategies. Rather, these criteria are designed to ensure that the resource's information, advice, and support are unbiased and evidence-based. By setting forth a requirement that the cessation resource provide evidence-based treatment strategies, the resource will be able to employ newer strategies as more research is done on the most effective approaches to smoking cessation treatments.

(Comment 161) Comments representing tobacco product manufacturers claimed that the criteria set forth in proposed § 1141.16 are unspecific or that this section uses vague terminology. One comment argued that the terminology is subject to conflicting interpretations.

(Response) We disagree. The criteria in the proposed rule, and generally adopted in this final rule, are extensive and detailed. In addition, the notice and comment process gave the public an opportunity to raise questions about our use and interpretation of specific terms. The proposed rule provided adequate detail for a number of comments to request revisions and clarifications. We have responded to the significant issues raised in the comments. As explained more fully in response to Comments 163 and 164, in the final rule, we revised the criteria to clarify that quitlines may tailor their services to meet the needs of individual callers and added more explanation and examples to the preamble to further clarify issues raised by comments. The criteria we are adopting will ensure that smokers using the referenced cessation resource receive unbiased and evidence-based services suited to their individual needs.

(Comment 162) Several comments that supported the choice of 1–800–QUIT–NOW as the cessation resource expressed concern that State quitlines would be subject to two sets of potentially inconsistent requirements because the CDC already maintains standards for these quitlines. These comments proposed that FDA specify that quitlines authorized by CDC for connection to the 1–800–QUIT–NOW network are qualified to be the cessation resource included on the required warnings.

(Response) We believe that it is important to establish criteria for the cessation resource as part of this rule to ensure that the standards reflected in these criteria will be followed for as long as the rule is in effect. We do not believe there will be any conflict between these criteria and CDC's requirements for State quitlines that are associated with our chosen resource (1–800–QUIT–NOW). We have worked closely with CDC regarding the choice of the cessation resource and the criteria that will be required. Moreover, CDC will include the criteria in this rule in its State grantee funding requirements, and will work with leading quitline experts to review, and where necessary, update existing scripting such as to accurately reflect current FDA-approved cessation medications.

(Comment 163) Many comments from public health advocacy groups and representatives of quitlines expressed concern about the criterion in proposed § 1141.16(b)(7) regarding providing information, advice, and support that is evidence-based, unbiased, and relevant to tobacco cessation. In particular, comments were concerned about the sentence in the preamble to the proposed rule that states that a cessation resource cannot include derogatory statements regarding cigarette manufacturers, importers, distributors, or retailers, or advocate public policy changes (75 FR 69524 at 69540). These comments asserted that the term ''derogatory statements'' is vague and could lead to challenges from industry. The comments asserted that the tobacco industry has made similar challenges in the context of interpreting the Master Settlement Agreement of 1998.

(Response) We disagree that the term ''derogatory statements'' is vague. Moreover, neither the proposed nor the final version of § 1141.16(b) or (c) includes that term. Instead, § 1141.16(b)(7) states a cessation resource must ''[p]rovide information, advice, and support that is evidence-based, unbiased (including with respect to products, services, persons, and other entities), and relevant to tobacco cessation.'' The focus of the cessation resource should be about changing a

smoker's behavior by providing factual information and evidence-based advice and support about tobacco cessation. Our purpose in adding to the preamble the example about derogatory statements was to emphasize that our chosen cessation resource must not provide biased information about, for example, tobacco companies. The preamble to the proposed rule contrasted derogatory statements as well as statements advocating public policy changes with factual information relevant to tobacco cessation. We conclude that this distinction should be retained in the final rule. Nonetheless, as discussed in the response to Comment 164, the final rule clarifies the distinction between providing factual information, advice, and support and providing biased opinions or advice.

(Comment 164) One comment representing quitlines expressed concern that many of the cessation resource criteria described in proposed § 1141.16(b) and the preamble to the proposed rule may interfere with the ability of counselors at a telephone quitline to tailor information to a specific caller. Specifically, this comment requested that FDA delete many of the criteria or clarify that they refer to the capacity of the quitline overall, and not to each interaction with a caller. Also, this comment requested that FDA either delete the term ''unbiased'' in proposed § 1141.16(b)(7), or define that term to include the concept of tailoring a call to the needs of an individual caller. In addition, this comment asked that FDA remove the word ''unbiased'' from proposed § 1141.16(d)(1) regarding staff training for a telephone quitline.

(Response) We agree that this issue needs to be clarified. It was not our intent that the criteria described in proposed § 1141.16 would limit the ability of the cessation resource to tailor an interaction to the needs of the individual smoker seeking help. In fact, as discussed below, we believe that one of the many benefits of choosing a telephone quitline as the cessation resource is the ability of the resource to tailor counseling sessions to individual callers. Although we do not agree that it is appropriate to delete any of the general criteria or the word ''unbiased'' from § 1141.16(b)(7), we have revised the rule to reorganize the criteria described in proposed § 1141.16(b) and (d). The final rule includes a paragraph (b) describing the types of services that a cessation resource must provide generally. The criteria in § 1141.16(b)(1) through (b)(7) were previously described in proposed § 1141.16(b)(1) through (b)(7), however, we revised the introductory language to clarify that a quitline may tailor individual calls as appropriate to meet the smoking cessation needs of individual callers. Thus, for example, if a caller says that he or she has attempted to quit many times and knows what to expect, the quitline does not need to provide factual information about what smokers can expect when trying to quit. Instead, the quitline might focus the counseling on practical advice about how to deal with common issues faced by users trying to quit or evidence-based information about effective relapse prevention strategies. In addition, we changed ''users'' to ''smokers'' in § 1141.16(b)(3) for consistent terminology with the rest of the paragraph.

The final rule also contains a paragraph (c) in § 1141.16 that addresses general requirements for the cessation resource, rather than the types of information to be provided to consumers seeking information or assistance. Section 1141.16(c) is primarily composed of the criteria in proposed § 1141.16(b)(8) through (b)(10) and (d). Except for the requirements regarding staff training and the maintenance of appropriate controls, this paragraph lists prohibitions for the cessation resource. For example, the cessation resource must not provide or otherwise encourage the use of any drug or other medical product that FDA has not approved for tobacco cessation. As described more fully in the response to Comment 166, we have clarified that the cessation resource may tailor information about cessation products to meet the particularized needs of an individual caller and may provide particular FDA-approved cessation products to callers, based on availability of those products to the resource. With respect to the comment expressing concern about the use of the term ''unbiased'' in the staff training criterion precluding the ability to tailor information, the revisions to paragraph (b) address concerns about the ability of cessation resource staff to tailor information to the needs of an individual caller. The criterion in paragraph (c) about staff training, when read in conjunction with paragraph (b), does not preclude tailoring of information during individual calls. Therefore, it is unnecessary to delete the term ''unbiased'' from § 1141.16(c)(8) to address this concern. We conclude that the revised criteria in paragraphs (b) and (c) of § 1141.16 will ensure that the cessation resource has the flexibility to provide counseling about smoking cessation that is appropriate to the needs of an individual caller while still ensuring that the resource does not provide opinions, advice, or support that are biased or not supported by appropriate evidence.

(Comment 165) One comment representing quitlines suggested that FDA either delete the criterion described in proposed § 1141.16(b)(10) that prohibits the cessation resource from encouraging ''the use of any non-evidence-based smoking cessation practices,'' or replace the word ''practices'' with ''treatment.'' This comment explained that practices such as coping strategies for dealing with cravings have not been as rigorously tested as medications and may not be considered evidence-based. This comment asserted that the criterion in proposed § 1141.16(b)(3), requiring a cessation resource to provide practical advice about how to deal with common issues faced by users trying to quit, adequately addresses this issue.

(Response) We understand the concerns expressed by this comment and agree that a cessation resource should be permitted to discuss coping strategies for dealing with cravings (*e.g.,* chewing gum) that may not have been rigorously tested in a scientific manner. However, because the distinction between treatment and practices is unclear, we conclude that a broad term such as ''practices'' is appropriate in order to ensure that evidence-based research is being used to provide callers with effective services. Using the broader term ''practices'' also avoids the possibility that definitional questions about whether something is a treatment will interfere with the ability of the cessation resource to provide effective cessation services to smokers. Deleting proposed § 1141.16(b)(10) completely, or replacing the word ''practices'' with ''treatment,'' may result in cessation resources encouraging non-evidence-based practices even though evidence-based practices are available. Section 1141.16(b)(3) permits the cessation resource to provide practical advice, and the practices described in the comment would be considered ''practical advice'' rather than ''non-evidence-based practices.'' In addition, as discussed in the comment, a cessation resource is permitted to tailor each counseling session to the needs of the individual caller.

(Comment 166) FDA received several comments relating to the cessation resource providing or discussing particular smoking cessation drug products. One comment representing a manufacturer of smoking cessation drug products suggested that the Agency permit the resource to provide one or more FDA-approved over-the-counter

cessation products, but not include language in the rule that prohibits the cessation resource from ''advertising or promoting a particular product.'' This comment claimed that there is evidence that recognizable brands of smoking cessation products can be important tools to promote cessation (Ref. 84). Comments representing telephone quitlines and a public health advocacy group requested that FDA clarify that simply mentioning a particular cessation product does not constitute advertising or promoting a particular product, so long as the resource makes clear it does not recommend the use of one cessation product or brand over another.

(Response) The final rule has been revised to clarify that a cessation resource may tailor a discussion of cessation medications for an individual caller. As noted in the preamble to the proposed rule, under the criteria the cessation resource may provide one or more FDA-approved over-the-counter cessation products, provided that it does so in a manner that does not advertise or promote a particular product (75 FR 69524 at 69540). We agree that, in the context of individual counseling, one medication may be suggested over another, based on an individual smoker's health needs and prior experience with cessation medications. For example, a quitline counselor may take into account warnings, precautions, and contraindications identified in the labeling of a specific drug product in relation to an individual caller. Also, a quitline counselor may suggest a particular medication based on the caller's prior experience with cessation medications (*e.g.,* not recommend a medication that previously caused significant side effects or did not work; recommend a medication that worked well in the past). In addition, a cessation resource may provide one or more FDA-approved over-the-counter cessation products, based on availability of the product(s) to the resource. A cessation resource may also mention the availability of free medication, provided it does so in a manner that does not advertise or promote a particular product. However, the resource must not advocate or promote a cessation product, such as by recommending the use of particular cessation products or brands over others to callers generally. All products that have been approved with smoking cessation claims have been found by FDA to be safe and effective for the approved indication. Even if there might be benefits associated with brand recognition for a smoking cessation drug product, we do not believe that it is appropriate for the cessation resource that we include in a required warning to promote any particular product.

(Comment 167) Several comments proposed that additional criteria be added to the criteria proposed in the NPRM. One comment suggested adding an additional criterion that the cessation resource must provide evidence-based advice regarding the protection of children and other nonsmokers from secondhand smoke. This comment reasoned that two of the warning statements address the dangers of secondhand smoke and the cessation resource should be prepared to counsel smokers who seek assistance after seeing these messages. Another comment recommended adding a criterion to prohibit the cessation resource from promoting a tobacco industry cessation program. This comment claimed that research has demonstrated that tobacco industry sponsored cessation resources either have no effect on smoking prevalence or actually cause increased smoking (Refs. 85 and 86). One comment from a submitter representing quitlines recommended the addition of a new criterion that would require the cessation resource to provide proactive, multi-call counseling services. The comment claimed that there is evidence these types of services are effective.

(Response) We recognize that there could be additional criteria for a cessation resource that would require the resource to provide broader services. However, we have designed the criteria in this final rule to focus on the minimum services that must be provided by an effective cessation resource and the minimum standards the resource must meet. We are mindful that existing cessation resources have varied budgets and do not want to require additional standards that, while possibly beneficial, would disqualify some effective treatment programs that do not have the resources to provide these services. We note, however, that the criteria described in § 1141.16 (b) and (c) do not preclude any cessation resource from providing additional unbiased, evidence-based cessation information, advice, and support. With respect to prohibiting the promotion of a tobacco industry cessation program on the basis that they are not effective, we conclude that the addition of a separate criterion is unnecessary. The cessation resource that will appear in the required warnings—1–800–QUIT–NOW—is run by government entities, and the criteria are designed to ensure that the resource provides cessation information, advice, and support that are unbiased and evidence-based.

(Comment 168) One comment recommended that an additional role of a cessation resource should be to direct smokers (who request it) to local specialist face-to-face treatment services and to provide accessible information on Medicaid, Medicare, and other large insurers' coverage for tobacco dependence treatment.

(Response) Our primary objective in requiring that referenced cessation resources comply with the criteria is to ensure that the cessation resource chosen provides evidence-based counseling to help smokers quit. Our criteria are designed to ensure that the cessation resource will continue to meet certain minimum standards. While not required by the criteria in this regulation, a referenced cessation resource is not precluded from providing additional relevant factual information, such as information about reimbursement for tobacco dependence treatments.

c. *Choice of cessation resource.* The NPRM did not specify a particular cessation resource. Rather, it noted that there are a number of possible alternatives, including use of an existing or new quitline or Web site, where smokers and other members of the public can obtain current unbiased, factual smoking cessation information (75 FR 69524 at 69540). Based on the information before the Agency, including the information provided in the comments, we have chosen the Network, which uses the toll-free telephone number 1–800–QUIT–NOW (1–800–784–8669), as the cessation resource to include on all nine required warnings. The Network is the single point of access to reach State-based quitlines in all 50 states, the District of Columbia, Puerto Rico, and Guam. Since 2005, CDC and NCI have partnered with States to create the Network. NCI manages the 1–800–QUIT–NOW telephone number, along with appropriate telecommunications and routing infrastructure, to ensure that calls are transferred to the appropriate State or territory quitline based on the area code of the caller. Calls from U.S. territories that do not have a quitline are routed to an NCI-run quitline. CDC and individual States or territories provide the funding for the quitlines. CDC provides funding through cooperative agreements as part of the National Tobacco Control Program.

As discussed more fully in the context of comments and responses in the following paragraphs, we find that this cessation resource, which was strongly

favored in many comments, will provide people in the United States with access to unbiased, evidence-based smoking cessation information, advice, and support. We have determined that including this cessation resource as part of the required warnings will increase the likelihood that smokers will quit smoking and thereby provide substantial public health benefits by reducing the life-threatening consequences associated with continued cigarette use. Therefore, we conclude that including a reference to 1–800–QUIT–NOW as part of all the required warnings is appropriate for the protection of the public health.

(Comment 169) Comments favoring inclusion of a cessation resource generally preferred the use of a telephone quitline. In particular, most of these comments advocated the use of 1–800–QUIT–NOW. The comments pointed to a robust body of evidence showing that proactive telephone counseling is effective in helping smokers to quit successfully. Several comments cited statistics from individual State quitlines about the types of services provided and success rates. In addition, several comments asserted that quitlines associated with 1–800–QUIT–NOW generally meet the criteria for a cessation resource specified in the NPRM.

Many comments discussed the advantages of choosing 1–800–QUIT–NOW. In support of the choice of a telephone quitline over a Web-based cessation resource, several comments noted the broad penetration of telephone access, including among low income and minority populations. These comments noted that Internet access has much lower penetration among the American public, particularly in many groups with high rates of smoking (*e.g.,* low income, low level of education). Many comments that advocated the use of 1–800–QUIT–NOW noted that it has an existing infrastructure that is available in all 50 states, the District of Columbia, Puerto Rico, and Guam. One comment stated that all quitlines associated with 1–800–QUIT–NOW are at least several years old.

Several comments argued that inclusion of 1–800–QUIT–NOW on cigarette packages could address issues relating to poorer smoking cessation outcomes among racial and ethnic minorities, as well as populations with low income and/or low education. One academic noted that smokers in these groups try to quit as often as other smokers but are less likely to use effective treatments (*citing* Ref. 87). The comment claimed that adding 1–800–QUIT–NOW to the required warnings holds unprecedented potential to close the gaps and disparities in treatment awareness and use. One comment representing a State quitline argued that quitlines can help address racial or ethnic disparities in access to effective tobacco treatment. For example, African-Americans have been significantly overrepresented among quitline callers in California, relative to the proportion of African-American tobacco users in that State. Several comments stated that quitlines provide services in languages other than English, particularly Spanish, and provide materials to important population groups (*e.g.,* youth, pregnant women, racial/ethnic populations). One comment representing a State quitline asserted that quitlines can help address disparities related to socioeconomic status. In California, utilization of quitline service is highest among low socioeconomic status tobacco users. This comment also claimed that the attractiveness of quitlines to tobacco users with low socioeconomic status is related to the fact that services are provided without a charge and are accessible by telephone, eliminating the need to arrange for transportation or child care. According to this comment, these factors can be significant barriers for individuals with modest resources. Another quitline provider stated that quitlines are disproportionately used by the chronically ill and those who are socially and economically stressed. This comment claimed that, arguably, these groups have the greatest need for support because they have a higher prevalence of smoking and are disproportionately affected by tobacco-related health concerns.

One comment representing a public health advocacy group pointed out that designation of a single quitline number would avoid the difficulty of manufacturers having to print different dialing information depending on where the cigarette package will be sold.

(Response) We agree with comments that a telephone quitline is the most effective means of ensuring that all Americans have access to unbiased, evidence-based smoking cessation information, advice, and support. We have decided to use the Network as the cessation resource and its portal number, 1–800–QUIT–NOW, will be included as part of electronic files for the required warnings that are available in the IBR document described in section V.B.4 of this document.

A key factor in our decision is that the evidence regarding the effectiveness of telephone quitlines is well documented. The 2008 PHS Guideline found that quitlines significantly increase abstinence rates compared to minimal or no counseling interventions. The 2008 PHS Guideline also found that use of quitline counseling in conjunction with cessation medication significantly improves abstinence rates compared to the use of medication with minimal or no counseling (Ref. 66 at pp. 91–92; *see also* Ref. 88). Consequently, quitlines are an important part of the HHS Tobacco Control Strategic Action Plan (Ref. 89).

In addition, there is evidence that knowing about the availability of a quitline increases quit attempts and successful cessation even among smokers who do not call the quitline (Ref. 88 (finding ''[t]elephone quitlines provide an important route of access to support for smokers, and call-back counselling enhances their usefulness'')). For example, one study of the effect of a smokers' hotline as an adjunct to self-help manuals found ''it is unlikely that higher abstinence rates among users [of the hotline] accounted for the total differences in outcome between hotline and manual only counties. It is possible that simply knowing that telephone help was there if needed enhanced abstinence even among nonusers'' (Ref. 82). A CDC report hypothesized that a possible explanation is that ''knowledge of cessation services, engendered through promotion, increases tobacco users' belief in the normalcy of quitting, which may lead to increased quit attempts among people who have access to the services, even those who do not use them'' (Ref. 90).

Another factor that we considered in choosing a telephone quitline is that telephone access within the United States is nearly universal. According to a 2010 Federal Communications Commission statistical report, household telephone subscribership in the United States was 96 percent in March 2010. This report shows that, even among households with annual incomes as low as $25,000, telephone penetration was over 90 percent in 2009, including among African-Americans and Hispanics (Ref. 91). Currently, Internet use and broadband penetration is much lower than telephone penetration in the United States, particularly among low income groups, certain racial and ethnic minorities, and households with low education levels (Ref. 92).

Beyond their wide accessibility, quitlines are also successful in helping certain high risk populations and other important demographic groups. One comment asserted that low income and uninsured smokers, those with the

lowest levels of formal education, and those in racial/ethnic populations with the highest smoking rates try to quit as often as other smokers, but are far less likely to use effective treatments. For example, smokers in several racial and ethnic groups attempt to quit as often as or more often than nonminority smokers but use effective treatments less often and have lower success rates (Ref. 66 at p. 156). Similarly, low socioeconomic status smokers or those with limited education express significant interest in quitting and appear to benefit from treatment. However, these smokers are less likely to receive cessation assistance (*Id.* at p. 151). One study concluded that non-Hispanic black and Hispanic smokers who attempted to quit smoking were significantly less likely to use cessation aids, and that this has implications for successful quitting among minority smokers (Ref. 87). Several comments, however, explained that at least some quitlines receive a disproportionate numbers of calls from certain minority or disadvantaged populations (*see, e.g.,* Ref. 93). In light of the overall low rates of calls to quitlines (approximately 1 percent of smokers call quitlines, although this percentage varies by State and how much the State promotes its quitline), even a disproportionately high volume of calls from important demographic groups is not enough to alter the overall quit rates for these groups. However, as discussed in section V.B.6.a of this document, there is strong evidence that there will be an increase in call volume to quitlines after the required warnings appear on cigarette packages and in cigarette advertising. This increase in use of quitlines could have an important impact on high risk and other important demographic groups if they continue to constitute a significant percentage of calls to quitlines.

In addition, a telephone quitline provides an excellent opportunity to tailor counseling sessions and provide additional materials for specific populations. The 2008 PHS Guideline also found that individually tailoring materials to address smoker-specific variables (*e.g.,* support sources available, time lapse since quitting, concerns about quitting) has been shown to be effective and have broad reach (Ref. 66 at p. 92). Several comments noted that virtually all State quitlines associated with 1–800–QUIT–NOW provide specialized materials to special populations, including pregnant women, racial and ethnic populations, and youth. Quitlines can also provide information (*e.g.,* about the negative health consequences of smoking or the health benefits of quitting) to smokers who are not ready to quit but who want additional information.

With respect to our choice of the Network and its telephone number, 1–800–QUIT–NOW, for the quitline cessation resource, we have determined that this resource will fulfill the goal to provide a place where smokers and other members of the public can obtain smoking cessation information from staffed trained specifically to help smokers quit by delivering current, unbiased, and evidence-based information, advice, and support. The quitlines that compose the Network, the telecommunications infrastructure supporting the Network, and the telephone number, 1–800–QUIT–NOW, are already well established and provide smoking cessation services to people throughout the United States. Comments that advocated the use of a specific quitline referred to 1–800–QUIT–NOW as the preferred cessation resource. By using an existing resource, infrastructure, and telephone number, we can leverage the Network's established structure and experience providing cessation services. This choice also avoids the costs associated with establishing a new quitline.

In addition, we agree with comments that the individual State and territory quitlines that are associated with 1–800–QUIT–NOW generally meet the criteria specified in § 1141.16(b). We understand, however, that these quitlines have some differences in funding resources and consequently provide differing levels of service. For example, some State quitlines provide longer hours of service than others. Based on the statistics provided in some comments, it is possible that not all of the individual State and territory quitlines associated with 1–800–QUIT–NOW meet all of the criteria we are adopting in § 1141.16(b). To assure that these criteria are met, CDC will include these criteria beginning with its 2013 National Tobacco Control Program funding opportunity announcement and HHS will monitor the quitlines for compliance with the criteria on an ongoing basis and will take appropriate steps to address any noncompliance.

(Comment 170) One medical organization suggested that the reference to the smoking cessation resource in the required warnings should also include a message encouraging smokers to contact their physician or health care provider. This comment cited studies to support the proposition that physician advice is effective in encouraging smoking cessation (*citing, e.g.,* Ref. 94). This comment also noted that both Australian and European Union graphic warnings recognize the role that physicians play in assisting patients' cessation efforts.

(Response) We agree that physicians, particularly primary care physicians, and other health care providers are a very helpful resource for encouraging smokers to quit (Ref. 66 at p. 35). However, we decline to include language on the required warnings encouraging smokers to see their doctor.

Many Americans do not have an ongoing relationship with a physician. Recent evidence indicates that the United States may be suffering from a shortage of primary care physicians, making it less likely that they would be available to provide cessation information to smokers (*see* Ref. 95 for statistics on decreasing numbers of U.S. medical school graduates selecting a family medicine career). In addition, unlike the selected quitline, we would not have a practical means to monitor health care provider compliance with the criteria the Agency is establishing in § 1141.16(b). Studies indicate that rates of physician adherence to similar practice guidelines for smoking cessation advice vary widely (*see* Ref. 96). For these reasons, it is preferable to include a reference to 1–800–QUIT–NOW on the required warnings. We note, however, that quitlines frequently refer people to their primary care physicians (*e.g.,* if a caller has further questions about the use of medications).

In addition, there is limited space available for including information about a cessation resource. The size of the required warnings is relatively small and the textual warning statement and color graphic image included in each warning must be clear, conspicuous, and legible as required by section 4 of FCLAA. In light of the limited space available, we have determined that including an additional message encouraging smokers to contact their physician or health care provider is not appropriate at this time.

(Comment 171) Some comments urged FDA to include a Web site as a cessation resource. Generally these comments suggested that a Web site would be a useful cessation resource in addition to a telephone quitline. For example, one public health advocacy group noted that there are advantages to utilizing both quitlines and Internet resources. According to this comment, while quitlines provide individualized telephone counseling, a Web site provides support 24 hours per day. One comment from a public health advocacy group claimed that about 10 million smokers search online for smoking cessation assistance every year, and it is

particularly important for the required warnings to include Web-based resources because there are a large number of Internet sites that ostensibly offer quitting assistance but do not offer evidence-based cessation help. Several comments acknowledged that the 2008 PHS Guideline did not find enough evidence to recommend computer-based interventions, but noted that the 2008 PHS Guideline also concluded that these interventions remain promising. Some comments also noted that Internet use is low in many groups with high rates of smoking (*e.g.,* low income, racial and ethnic minority groups). However, several comments advocating inclusion of a Web site resource noted that many cessation services, including many quitlines and health plans, are utilizing the Internet to provide combined telephone counseling and Web-based cessation treatment. One comment suggested that as American culture adopts different forms of communication, it will be important to assess the effectiveness of using new technologies and approaches. This comment encouraged FDA to fund research to learn which approaches will encourage the most people to quit smoking.

One comment from the tobacco industry claimed that reference to a smoking cessation Web site may raise additional implementation issues and requested an opportunity to comment in advance of such a requirement. This comment did not identify any specific issues associated with reference to a smoking cessation Web site.

(Response) We recognize that Web sites are another important source of smoking cessation information and interventions. Although the 2008 PHS Guideline did not recommend the use of Web-based interventions, it concluded that ''[g]iven the potential reach and low costs of such interventions * * * they remain a highly promising delivery system for [treating] tobacco dependence'' (Ref. 66 at p. 94). We also recognize that Internet use is highest among younger populations, and thus might be a useful tool to intervene with young smokers, given that maximum cessation benefits are gained by quitting at a younger age. Furthermore, Web sites can provide information to smokers who are not ready to quit but who are seeking additional information about cessation.

However, we have decided not to include a Web site as the cessation resource incorporated in the required warnings. For the reasons explained more fully above, we find that a telephone quitline is a better overall cessation resource than a Web site. There is stronger scientific support that telephone quitlines are effective, they are more widely available to a broader cross section of Americans, particularly groups with higher rates of smoking and lower access to cessation services, and there is a strong national quitline infrastructure in place. In light of the limited space available on the required warnings and the need to ensure that the graphic images and textual warning statements are clear, conspicuous, and legible, we do not think it is appropriate at this time to include both a telephone quitline and a Web site address on all required warnings. We intend to evaluate this possibility in the future when we are designing and testing revised versions of the required warnings.

d. *Implementation issues.* Proposed § 1141.16(a) stated that a required warning must include a reference to a smoking cessation assistance resource as specified in the IBR document. The preamble to the proposed rule explained that the smoking cessation information would be included as part of the required warning and would not appear outside of the areas specified for the required warning. In other words, the cessation resource would be within the top 50 percent of the front and rear panels of cigarette packages and within the 20 percent of the area of advertisements occupied by the required warning (75 FR 69524 at 69541). We received several comments regarding how a cessation resource should appear in the required warning and other implementation issues relating to inclusion of a cessation resource in the required warning. These comments and our responses are summarized in the following paragraphs.

(Comment 172) A comment representing small tobacco product manufacturers expressed confusion about whether FDA would add the reference to a cessation resource to the required warnings or whether a manufacturer would have to select the cessation resource and incorporate it into the required warning. The comment noted a preference that FDA provide the specific language for the cessation resource. However, one small tobacco product manufacturer asked that FDA provide a variety of options for cessation resources and include those options in the electronic files for the required warnings provided by the Agency.

(Response) We have selected 1–800–QUIT–NOW as the cessation resource that must appear on the required warnings. The required warnings in the IBR document include the reference to the cessation resource, 1–800–QUIT–NOW. We disagree with the request that we provide a variety of options for cessation resources and include those options in the electronic files for the required warnings. Such an approach could be confusing to consumers, because the required warnings would appear with a different cessation resource on different packages of cigarettes and in different advertisements. Also, it would be difficult to monitor many cessation resources to ensure that each one meets the criteria established in § 1141.16(b) and (c). By choosing one, existing toll-free telephone number that is under the control of NCI, provides access to consumers throughout the country, and includes State quitlines that have cooperative agreements with CDC, we have assurances that our cessation resource criteria will be followed.

(Comment 173) Several comments mentioned that an increase in the volume of calls to State quitlines may increase funding needs. These comments suggested that additional resources should be provided to State quitlines.

(Response) We expect that inclusion of 1–800–QUIT–NOW on the required warnings will increase the volume of calls to State quitlines. While some quitlines may currently have some additional capacity, there will likely be need for additional resources. In the fiscal year 2012 President's Budget, there is $25 million from the Prevention and Public Health Fund allocated for CDC to spend on the National Network of Tobacco Cessation Quitlines. Additionally, the Centers for Medicare and Medicaid Services is working with the State Medicaid Directors to permit tobacco quitlines as an allowable Medicaid administrative activity.

(Comment 174) One comment encouraged FDA to require that the cessation resource be displayed as a telephone number (1–800–784–8669) in addition to 1–800–QUIT–NOW because some wireless phones do not have letters on the keypad. However, another comment representing a quitline expressed the view that it is important to use the letters in 1–800–QUIT–NOW rather than the telephone number because it is itself a cogent cessation message.

(Response) We agree there would be benefits to identifying the cessation resource using 1–800–QUIT–NOW as well as the telephone number 1–800–784–8669. However, as explained previously, there is very limited space for identifying the cessation resource. The use of 1–800–QUIT–NOW is a way to provide the number for people to call

while in the same space providing information about what the number is for. Using less space for the cessation resource helps ensure the required warning remains clear, conspicuous, and legible and appears within the specified area. Moreover, the use of letters is likely to be easier for people to remember. The Agency also believes most telephones in use still include letters on keypads and that toll-free telephone numbers are frequently identified using these letters. As stated previously, we will also conduct research and keep abreast of scientific developments regarding the efficacy of various required warnings and the types and elements of various warnings that improve efficacy, including elements related to identifying cessation resources.

(Comment 175) Several comments addressed the words that would signal the appearance of a cessation resource. These comments described experience from New Zealand that showed increases in both quitline number recognition and the number of callers reporting cigarette packages as the source for learning the quitline number after the introduction of new graphic warnings with a redesigned reference to a cessation resource (*i.e.,* ''You CAN quit smoking. Call Quitline 0800 778 778, or talk to a quit smoking provider''). The prior warning said ''For more information call'' next to a telephone number. According to one study, there was a 24 percent increase in reported recognition of the quitline number after this change (Ref. 69). Also, in the first full year after the introduction of the new graphic warnings, the volume of calls to the quitline increased significantly and 26 percent of callers reported cigarette packages as the source of the number (compared to 7.5 percent the prior year) (*Id.,* Wilson 10/10). One academic researcher suggested a short, direct ''call to action'' phrase to motivate cessation behavior. Similarly, another comment from an academic institution suggested that the warnings provide the smoker with avenues to take in order to quit and simultaneously instill confidence in the user that he or she can take action.

(Response) As stated previously, there is limited space for the cessation resource on the required warnings. Therefore, we have determined that the cessation resource will be identified solely by the telephone number 1–800–QUIT–NOW. In the limited space available, we have determined that this telephone number and its context provide sufficient information such that viewers will understand that a call to the telephone number will provide information, advice, and support regarding smoking cessation.

(Comment 176) One comment from an academic institution encouraged FDA to require, in addition to a quitline number, clear encouragement of action steps for quitting. This comment recognized that space on the required warnings is limited and suggested that package inserts and onserts are one way of accomplishing this without compromising the visual impact of the graphic warnings.

(Response) A requirement to add onserts or inserts is beyond the scope of this rulemaking and, therefore, we decline to require them here.

VI. Comments Regarding Implementation Issues

A. Technical Issues Regarding Compliance

Section 1141.12 refers to ''Cigarette Required Warnings,'' which is incorporated by reference (IBR) in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The IBR document includes electronic files of images that must be included on all cigarette packages, and in all cigarette advertisements.

In response to the proposed rule, some comments, including comments from cigarette manufacturers and tobacco industry trade associations, raised issues relating to the electronic files and the implementation of the graphic warnings on cigarette packages and in cigarette advertisements. Those comments, and FDA's responses, are discussed in the following paragraphs.

(Comment 177) Comments from two tobacco product manufacturers stated that they would need to make certain technical adjustments to the single sized graphic warnings published with the proposed rule in order to ensure that the warning fits packaging of varying sizes and shapes. According to the comments, if FDA provided only the single warning format published with the proposed rule, the company would need to adjust the height-to-width ratio (*i.e.,* aspect ratio) of that warning in order to cover 50 percent of the front and rear panels of various package configurations. However, adjusting the aspect ratio, such as by elongating or compressing the warning, could distort the graphic image and/or textual warning statement. These comments recommended that FDA ensure that manufacturers are able to adapt the graphic warnings to fit cigarette packages of varying sizes and shapes and provide guidance about how to adapt the warnings.

(Response) We agree that the size and shape of certain packages might require companies to adapt the electronic files provided in the IBR document. To help prevent distortion of the image and text and to minimize the need for adaptation, we are providing electronic files in different formats designed to fit packaging of various sizes and shapes. We are adding language to the IBR document that provides instructions as to when each of the formats must be used. The instructions are based on the aspect ratio of the display area where the required warning must appear. This language also describes the requirements companies must follow when adapting the electronic files provided in the IBR document. For example, the requirements state that each of the different elements of the warning (*i.e.,* the image, the textual warning statement and reference to the cessation resource) must, to the extent possible, maintain the relative scale and proportions of the elements as displayed in the relevant electronic file, and the positions of each of these elements must be maintained relative to each other.

(Comment 178) Two comments from cigarette manufacturers requested clarification concerning how companies should incorporate the required warnings on packages with hinged lids. These comments stated that the content of warnings printed on the hinged lids can shift up or down by about 1 mm at the point where the lid meets the front of the pack due to normal variations in production of the packaging. These comments recommended that FDA design the warnings with all text located either above or below the hinged lid, or allow for minor variations in how the graphic warnings appear on cigarette packs due to this manufacturing variability.

(Response) We agree that the integrity of the warning must be maintained on packages to ensure that the warning is clear and legible. To clarify the requirements that companies must follow when they adapt the electronic files for hinged lid packages, we have added language to the IBR document that permits companies to separate two lines of text within the textual warning statement so that the line at the location where the lid is to open cuts across the background space between two lines rather than through a line of text. This provision will allow companies to adapt the electronic files provided in the IBR document to ensure that the textual warning statement is not severed when the package is opened and is clear, conspicuous, and legible in accordance with section 4 of FCLAA. According to this language in the IBR document, companies are specifically prohibited from severing any word in the textual

statement and are required to ensure that the integrity of the warning will be restored when the package is closed. We note that product packages with hinged lids are widely prevalent in countries that already require graphic warnings and, based on that experience, we conclude that this new provision should provide companies with the flexibility that they need for displaying the warnings on packages with hinged lids.

(Comment 179) Two comments, from a cigarette manufacturer and a tobacco company trade association, raised a concern about incorporating the required warnings on ''soft pack'' style packaging. These comments stated that ''soft pack'' style packaging is manufactured through a process in which the top of the package is folded down after cigarettes are inserted and held together by a small overwrap closure, or ''stamp.'' Historically, the closure is made of opaque paper and applied with glue to hold the package in place. According to these comments, the closure hangs down approximately 0.375 inches over the top center of the front and back panels of the package. The closure would obstruct any text or image appearing under it. According to these comments, it is not technically feasible to make a clear or transparent closure that will adhere to the package. One comment recommended that FDA amend the proposed rule to permit that graphic warnings for soft packs appear at the bottom of the individual pack, or to specifically allow the closures at the top center of the pack. The other comment recommended that FDA use enforcement discretion to permit the closure on soft packs until a technologically feasible solution is developed.

(Response) We recognize the technological difficulty of incorporating the required warnings on ''soft pack'' style packaging. Given the paramount need to incorporate the warning without obstructing any of the discrete elements of the warning (*i.e.,* the image and the textual warning statement) or the reference to a cessation resource, the final rule permits companies to adapt the warnings on ''soft pack'' style packaging by moving the warning below the closure in accordance with the requirements included in the IBR document. The IBR document states that this is only permitted when it is not technologically feasible to incorporate the required warnings on ''soft pack'' style packaging without the need to adapt the warning as set out in the electronic files provided in the IBR document. The requirements included in the IBR document allow companies using ''soft pack'' style packaging only to move the upper boundary of the display area of the warning so that it runs along a line that is parallel to and not more than 0.375 inches from the top edge of the package. The companies compress the vertical size of the image and then shift it down (so that it stays within the top 50 percent of the package). This language also requires companies who do this to ensure that, to the extent the file must be adapted to fit the dimensions of the warning area below the closure, the proportions of the required warning must be maintained. In addition, the instructions in the IBR document specify that the closure and the portion of the packaging that appears between the top edge of the package and the upper boundary of the display area of the required warning must be either solid black or solid white. This will allow companies to continue to produce ''soft pack'' style packaging with closures at the top center of the pack without obstructing the required warning. However, if we determine that it would be technologically feasible to incorporate the required warnings on ''soft pack'' style packaging without the need to adapt the warning as set out in the electronic files provided in the IBR document, we plan to notify the regulated companies and the public of this conclusion and give regulated companies a reasonable amount of time to modify their packaging before any regulatory action is taken under this rule. We decline to change the final regulation to permit graphic warnings on ''soft pack'' style packaging to appear at the bottom 50 percent of the packaging. We have determined that requiring that the warnings appear in the upper portion of the package, as specified by the Tobacco Control Act, will result in warnings that are more prominent, more salient, and more effective than warnings appearing at the bottom of the package.

(Comment 180) Two comments, from a cigarette manufacturer and a tobacco company trade association, noted that cigarette packages are typically wrapped in clear cellophane with a tear tape located in the upper 50 percent of the package. The tear tape permits an individual to open the package, and usually is removed once the package is opened for the first time. One comment stated that the cellophane tear tape will obstruct the required warning when the cigarette package has not yet been opened for the first time, and recommended that FDA expressly permit the use of tear tapes and require that warnings for ''soft pack'' style packaging appear at the bottom of the packaging. The other comment recommended that FDA permit the use of tear tapes and that the Agency use enforcement discretion to allow companies to potentially obstruct the required warning before the package is opened for the first time.

(Response) We have determined that companies can use cellophane tear tapes, and the final regulation does not prohibit such use on cigarette packaging. We further have determined that it is technologically feasible to use clear tear tape in a manner that does not obstruct the required warning before the cigarette package is opened for the first time, and note that clear tear tape is widely used on product packaging in other countries that require graphic warnings. We are not aware that this has created any substantial technical difficulty in the production of cigarette packages, nor are we aware that clear tear tape has led to any significant obstruction of the graphic warnings. If a company has a unique problem with regard to its packaging, it should raise this issue with us, and the difficulty can be addressed on an individual basis. We decline to change the final regulation to allow the required warnings to appear on the bottom 50 percent of the packaging. We have determined that requiring that the warnings appear in the upper portion of the package, as specified by the Tobacco Control Act, will result in warnings that are more prominent, more salient, and more effective than warnings appearing at the bottom of the package.

(Comment 181) Comments from two companies raised concerns about their ability to incorporate the required warnings in advertisements of varying sizes and shapes. These comments noted that the proposed FDA rule requires that companies maintain the aspect ratio of the warnings as set forth in the electronic files. The comments stated that it would not be possible to maintain the clarity of the warning in certain advertisements if companies are required to use the 4:3 aspect ratio set out in the advertisement format published with the proposed rule. One company recommended that FDA provide warnings with different aspect ratios (1:1, 1.5:1, 1:2, 2:1, and 2.5:1) to address this concern. The other company recommended that FDA either eliminate the requirement that companies maintain the aspect ratios set out in the electronic files or allow companies to adjust the layout of the warnings so long as the manufacturer includes both the image and the textual warning statement.

(Response) We have revised the proposed IBR document and the

electronic files provided in the final IBR document include warnings designed with a variety of different aspect ratios. Specifically, the files are designed with aspect ratios of 1:1, 1.5:1, 1:2, 2:1, and 2.5:1. As provided in § 1141.10, the required warnings must be accurately reproduced in advertisements. Therefore, companies should choose an aspect ratio that is appropriate for the dimensions of their advertisement such that the required warning can be reproduced accurately once it is sized (*i.e.,* expanded or compressed) to occupy the required area of the advertisement. These files will permit companies to incorporate the required warnings into their advertisements without significant distortion or loss of clarity.

(Comment 182) One comment from a tobacco product manufacturer recommended that FDA provide 5.5 inch wide and 27 inch wide formats for advertisements. The comment stated that expanding a required warning more than 150 percent or compressing it down to less than 30 percent of the original image will result in a loss of image clarity. The comment stated that providing required warnings in the 5.5 inch and 27 inch sizes will allow it to incorporate the warnings into the range of advertisements it uses without any loss of clarity.

(Response) The electronic files provided in the IBR document include formats for advertisements in 5.5 inch wide and 27 inch wide sizes.

(Comment 183) One comment from a tobacco product manufacturer noted that FCLAA requires advertising warnings to have a rectangular border that is the width of the first down stroke of the capital ''W'' of the word ''WARNING'' in the textual warning statements. The comment went on to state that FDA's various proposed required warnings have different-sized ''W's'' in the word ''WARNING,'' and requested that FDA permit manufacturers to apply a uniform border width across the nine required warnings for consistency.

(Response) The electronic files provided in the IBR document have a uniform border built into the formats for required warnings to be used in advertisements. We have exercised our authority under section 201 of the Tobacco Control Act to adjust the statutory requirement that the border of the warning be the width of the first down stroke of the letter ''W'' in the word ''WARNING'' in the textual warning statement. A uniform border requirement for all advertisements will ensure that the warnings are clear, conspicuous, and legible, and appear within the specified areas, especially given the variety of font styles included in the nine selected warnings.

(Comment 184) Several comments requested that FDA provide fonts for the textual warning statements in each of the required warnings.

(Response) For English and Spanish language warnings, the font size and font style is built into the electronic files provided in the IBR document. For advertisements in foreign languages other than Spanish, companies must comply with the font size requirements in section 4(b)(2) of FCLAA and any format requirements included in the IBR document. In all situations, it is the advertiser's responsibility to ensure that the textual statements appear in conspicuous and legible type and that the required warning complies with the format specifications set forth in section 4 of FCLAA.

(Comment 185) One comment requested that FDA provide instructions on how companies should combine and display the images developed for use in small advertisements less than 12 square inches with the required textual warning statements.

(Response) We recognize that the small size of these advertisements presents additional challenges. We are providing an electronic file of the graphic that must be used for warnings appearing in advertisements that are less than 12 square inches. Companies may combine the graphic and the textual warning statement or otherwise adjust the layout of the warning so long as each warning includes the specified graphic and an appropriate textual warning statement. It is the advertiser's responsibility to ensure that the textual warning statement appears in conspicuous and legible type and that the combined warning complies with the format specifications set out in section 4 of FCLAA.

(Comment 186) Several comments recommended that FDA require that companies reproduce the color graphics in the industry standard four-color (CMYK) printing process.

(Response) The electronic files provided in the IBR document were built with CMYK printing standards. The directions in the IBR document specify the use of CMYK printing standards.

(Comment 187) One comment requested that FDA make available ''printers proofs'' for each of the required warnings in order to ensure optimal clarity.

(Response) We have determined that the electronic files provided in the IBR document will be adequate to ensure necessary clarity. Thus, we do not believe it is necessary to provide ''printers proofs'' for the warnings.

(Comment 188) One comment requested that FDA adopt required warnings with consistent dimensions to allow for accurate incorporation into manufacturers' packages and advertisements.

(Response) We decline to adopt this recommendation. As discussed previously, our selection of the nine final required warnings was based in part on our desire for a diverse set of warnings in a variety of different styles (*e.g.,* photographic and illustrative, different fonts and font sizes) and diversity of human images (*e.g.,* race, gender, age) in order to reach the broadest range of target audiences. We have determined that this variety will enhance the effectiveness of the warnings and help to delay potential wear out of the warnings. Because of the diversity of styles and images, some warnings have slightly different dimensions than others.

(Comment 189) One comment recommended that FDA provide layered high resolution .tif or .eps files, with text supplied as a separate layer. Another comment recommended that FDA provide images as .jpeg files.

(Response) The electronic files included in the IBR document are built as .eps files, with separate layers for text and images. Companies will be able to convert the files into .jpeg files if needed.

B. Textual Statement Color Formats

In the document entitled ''Proposed Required Warning Images'' included in the docket for the NPRM, FDA provided two formats for each proposed required warning; one with the warning statement in white text on a black background and one with the warning statement in black text on a white background, under section 4(a)(2) and (b)(2) of FCLAA. Several comments offered suggestions regarding the use of the color combinations, which we have summarized and responded to in the following paragraphs.

(Comment 190) A few comments suggested that FDA specify that the required warnings on cigarette packages and advertisements contain required warnings in *either* the white text on black background format or the black text on white background format, whichever the Agency chooses to most effectively communicate the warnings.

(Response) We disagree. Section 4(a)(2) of FCLAA states that for cigarette packages, the ''text shall be black on a white background, or white on a black background.'' Similarly, for advertisements, section 4(b)(2) of

FCLAA states that the text of the statement in the required warning ''shall be black if the background is white and white if the background is black.'' We interpret these statutory requirements to mean that companies can use either of these two text/background color combinations on the package or in the advertisement.

(Comment 191) One comment recommended that the word ''CANCER'' always appear in red as part of the health warnings on cigarette packages and advertisements.

(Response) We disagree. As stated previously, section 4(a)(2) and (b)(2) of FCLAA prescribe the colors for the textual statements on packages and advertisements (*e.g.,* white text on black background or black text on white background). FDA has the authority to change the format of the textual statements if such a change would promote greater understanding of the health risks associated with cigarette smoking. If we determine at a later date, that requiring the word ''CANCER'' to appear in red font will promote a greater understanding of smoking's risks, we may propose new iterations of the required warnings in future rulemakings.

C. Random Display and Rotation of Warnings

The proposed rule did not specifically address the statutory requirements for the warnings on cigarette packages to be randomly displayed in each 12-month period and for quarterly rotation of warnings in advertisements, under section 4 of FCLAA. However, FDA received several comments on this issue. These comments, and FDA's responses, are included in the following paragraphs.

(Comment 192) One comment expressed concern that cigarette manufacturers may only use some of the nine new required warnings on their cigarette packages and requested that FDA require companies to use all the required warnings in equal numbers.

(Response) We agree that all cigarette manufacturers must use all of the nine required warnings on their cigarette packages. Section 4(c)(1) and (c)(3)(B) of FCLAA expressly requires that the nine required warnings must be randomly displayed in as equal a number of times as possible on each brand of cigarette product and be randomly distributed in all areas of the United States so that all of the required warnings appear in the marketplace at the same time.

(Comment 193) One comment recommended that retailers be exempted from any requirement to rotate the required warnings for each brand they sell in stores.

(Response) We decline to address this issue here, as it is beyond the scope of the current rulemaking.

(Comment 194) Several comments recommended that FDA rotate the graphic warnings to prevent overexposure. The comments also noted that different warnings will have different impacts on the various segments of the population, further emphasizing the need to rotate the warnings.

(Response) It is unclear whether these comments were referring to the quarterly rotation of the required warnings in advertisements or the need to refresh the warnings on a regular basis. We agree that rotation of the warnings is important to delay wear out and to ensure that all population segments are exposed to the different warnings in as equal a number of times as is possible. In accordance with section 4(c)(2) of FCLAA, the required warnings must be rotated quarterly in cigarette advertisements. See section II.E of this document for additional information regarding FDA's efforts to delay or prevent wear out.

(Comment 195) One comment recommended that FDA monitor the rotation of required warnings in cigarette advertisements to ensure compliance by all manufacturers, distributors, importers, and retailers.

(Response) We agree with this comment. We will monitor rotation and ensure compliance, which will include the review and approval of warning plans submitted to the Agency in accordance with section 4(c) of FCLAA.

(Comment 196) One comment suggested that manufacturers be given broad discretion in complying with the requirements that they include the required warnings on all cigarette packages such that in each 12-month period all of the different warnings appear in as equal a number of times as is possible on each brand of the product (*see* 15 U.S.C. 1333(c)). The comment stated that its printing machines, and in particular the print cylinders, used to produce ''soft pack'' style packaging only allows the company to print five images per roll and does not allow for warnings to be die cut and collated. Because ''soft pack'' style packaging only accounts for about 10 percent of all packages distributed and sold, this style of packaging frequently is printed in small batches and for some, is printed only once per year. The comment stated that in light of these production constraints, it would be impossible to apply and distribute ''soft pack'' style packages displaying the nine required warnings randomly and in approximately equal numbers. The comment recommended that, for ''soft pack'' style packages, FDA apply a policy of enforcement discretion that relieves companies of the obligation to display the nine required warnings randomly and equally as long as companies have taken reasonable steps to distribute the warnings as randomly and equally as possible. Another comment expressed general concerns about a manufacturer's ability to comply with the requirement that the warnings be randomly displayed in as equal a number of times as possible.

Several comments requested additional guidance on the filing of warning plans, including how to hold parties responsible for meeting FCLAA and the Tobacco Control Act's rotation and random display requirements.

In addition, one comment asked that FDA adopt a formal process for approval of required warnings on packages and warning plans. Some comments from manufacturers suggested that, to add predictability for companies on the transition to the new warnings, FDA should consider adopting a procedure to allow pre-approval or pre-submission review of cigarette packaging and advise manufacturers of any deficiencies so the manufacturer can remedy them before production. One comment requested that FDA use Federal Trade Commission (FTC) procedures for pre-approval review of packaging.

(Response) We have opted not to address these issues as part of this rulemaking proceeding. Under section 4(c) of FCLAA, warning plans must be submitted to FDA for approval. As noted in the NPRM, we intend to separately address the requirements of section 4(c) of FCLAA related to the submission of plans regarding the random display of warnings on packages and rotation in advertisements (75 FR 69524 at 69538). This is still our plan, and we believe the issues raised in these comments would be better addressed in that context.

(Comment 197) One comment suggested that FDA provide sample pre-approved layouts for required warnings on cigarette packages.

(Response) By providing the electronic files of the required warnings, we are providing formats that the companies must use for their packages. The final rule includes a document incorporated by reference, entitled ''Cigarette Required Warnings,'' which contains the final images to be required on cigarette packages. Cigarette manufacturers also should refer to § 1141.10(a), which mandates that the required warnings be on the top 50

percent of both the front and back of the cigarette packages.

(Comment 198) One comment requested that FDA issue a tobacco product advertising guide for industry. This comment noted that while product labeling and advertising present some similar issues, there are specific issues that relate solely to advertising communications with consumers. Another comment suggested that FDA should issue separate advertising guidance for industry that includes recommendations for display of required warnings in each common advertising form.

One comment stated that FDA should require that cigarettes displayed at the point of sale should be required to be displayed in a manner so that the graphic warnings are visible.

One comment submitted on behalf of several nonprofit organizations suggested that FDA modify proposed § 1141.10 to include two paragraphs regarding the use of images of cigarette packs in advertisements and in other communications. They requested that FDA add one paragraph to state that any image of a cigarette pack in an advertisement must include a required warning on the cigarette pack image. In addition, they requested that FDA add a paragraph to state that no manufacturer, importer, distributor, or retailer may alter any image used to depict cigarette packs as legally distributed or sold to consumers in any public communication (including, but not limited to, movies, Web sites, and television programs) so that the required warning on the cigarette pack image is removed or obscured in any way.

(Response) We recognize that the range of advertising materials covered by the new graphic warning rules may create additional complexities. As stated previously, we intend to issue separate regulatory documents to provide information on compliance with the random display and rotation requirements. We will consider whether any other actions that are within the scope of our authority under the Tobacco Control Act may be warranted, such as addressing requests for additional guidance regarding advertising or suggested regulatory changes.

VII. Legal Authority and Responses to Comments

A. FDA's Legal Authority

As set forth in the preamble to the proposed rule (75 FR 69524 at 69524 through 69525), the Tobacco Control Act provided FDA with the authority to regulate tobacco products, and section 201 of the Tobacco Control Act modifies section 4 of FCLAA to require that nine new health warning statements appear on cigarette packages and in cigarette advertisements and to require that ''the Secretary [of Health and Human Services] shall issue regulations that require color graphics depicting the negative health consequences of smoking'' to accompany the nine new health warning statements.

Under section 4(d) of FCLAA (as amended by section 201(a) of the Tobacco Control Act), FDA may adjust the type size, text, and format of the required warnings as FDA determines appropriate so that both the textual warning statements and the accompanying graphics are clear, conspicuous, and legible and appear within the specified area. Furthermore, section 202(b) of the Tobacco Control Act amends section 4 of FCLAA to permit FDA to, after notice and an opportunity for the public to comment, adjust the format, type size, color graphics, and text of any health warning statement if such a change would promote greater public understanding of the risks associated with the use of tobacco products.

In addition, provisions of the FD&C Act provide authority to require disclosures. For example, section 906(d) of the FD&C Act (21 U.S.C. 387f(d)) authorizes FDA to issue regulations restricting the sale or distribution of cigarettes and other tobacco products, including restrictions on the advertising and promotion of such products, if FDA determines the restriction is appropriate for protecting the public health.

These requirements are supplemented by the FD&C Act's misbranding provisions, which require that product advertising and labeling include proper warnings (*see* 21 U.S.C. 321(n); 387c(a)(1), (a)(7)(A), (a)(7)(B), and (a)(8)(B)). In addition, under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA has authority to issue regulations for the efficient enforcement of the FD&C Act.

While we did not receive comments regarding our authority to issue these regulations under the provisions referenced in the previous paragraphs, we did receive comments regarding the constitutionality of the warning requirements, which are summarized and responded to in sections VII.B and VII.C of this document.

B. First Amendment Commercial Speech Issues

FDA received several comments related to First Amendment commercial speech issues. These comments are summarized and responded to in the following paragraphs.

(Comment 199) Several comments from the tobacco industry, advertising industry associations, and private citizens expressed concern that the graphic warning requirements proposed by FDA violate the First Amendment of the United States Constitution. Specifically, comments alleged that the proposed required warnings are unconstitutional because, rather than conveying factual information to consumers, they contain ''disturbing,'' ''lurid'' images that are designed to elicit emotions, such as ''loathing, disgust, and repulsion.'' Thus, the comments state, they force tobacco companies to ''stigmatize their own products'' and compel them to convey the government's ''ideological message'' that ''the risks associated with smoking cigarettes outweigh the pleasure that smokers derive from them'' and that no one should use these lawful products. The comments also asserted that the warning requirements are unjustified because the health risks of smoking are already well known, and that they are unduly burdensome because the size and positioning requirements for the warnings on packages and advertisements would effectively rule out the companies own attempts to convey information about their products. For these reasons, the comments asserted that the graphic warning requirements constitute compelled speech regulation that is content-based and presumptively invalid and that the requirements can only be upheld if they satisfy strict scrutiny, *i.e.,* if they further a compelling government interest by the least restrictive means available. The comments stated that the graphic warning requirements cannot satisfy this standard because they will have no material impact on consumers' beliefs about the health risks of smoking or on smoking behavior and because the government bypassed less speech-restrictive alternatives in favor of the requirements.

The comments from the tobacco industry also stated that the warning requirements violate the First Amendment because they restrict tobacco companies' speech. They stated that requiring the warnings to occupy the top 50 percent of the front and back display panels of cigarette packages and the top 20 percent of cigarette advertisements impairs the communication value of the tobacco product manufacturers' trademarks and trade dress and narrows their avenues of communications with adult smokers, which are already limited because of the

Master Settlement Agreement and the other requirements of the Tobacco Control Act. Indeed, one of the comments argued that relegating tobacco companies' message to the bottom half of cigarette packages would render their speech on packaging ''wholly ineffective'' and that the collective requirements with respect to packaging and advertisements would ''effectively rule out'' the companies' attempts to convey information about their products to consumers. The comments asserted that the warning requirements do not satisfy the test governing restrictions on commercial speech articulated by the Supreme Court in *Central Hudson Gas & Electric Corp.* v. *Public Service Commission,* 447 U.S. 557 (1980), which requires that government restrictions on commercial speech directly advance a substantial government interest and be no more extensive than necessary to serve that interest. Similar to their assertions with respect to compelled speech, the comments asserted that, to the extent that the warning requirements restrict speech, they do not pass muster under the First Amendment because they will have no material impact on consumers' beliefs about, or understanding of, the health risks of smoking or on smoking behavior, and because the government bypassed less speech-restrictive alternatives in favor of the requirements.

Other comments, including comments from a law firm, a public health advocacy group, and a private citizen, disagreed that the warning requirements violate the First Amendment. Specifically, two comments noted that the warning requirements have been upheld by a Federal court in *Commonwealth Brands* v. *United States,* 678 F. Supp. 2d 512, 529–32 (W.D. Ky. 2010), *appeal pending sub nom., Discount Tobacco City & Lottery, Inc.* v. *United States,* Nos. 10–5234 & 10–5235 (6th Cir.). One comment noted that the court rejected an argument that the new warnings required under the Tobacco Control Act are too large and too prominent and stated that Congress has made findings with respect to the required size of the warnings, their placement on packages and advertisements, and the text of the warnings based on a substantial record. The comment also stated that Congress' findings are supported by the voluminous authority cited in FDA's NPRM. Another comment stated that, although tobacco companies will have to redesign their packages as a result of the warning requirements, they will still be able to communicate with their customers through packaging, advertising, and other channels. In addition, the comment stated that the warning requirements do not offend manufacturers' First Amendment rights because the required warnings are factual disclosures that accurately depict the real consequences of smoking cigarettes and the benefits and importance of quitting. The comment asserted that the warning requirements support the public interest by providing consumers with truthful information that is helpful in making informed purchasing decisions. The comment also stated that the government constitutionally regulates the advertising and labeling for a wide variety of industries in the interest of providing consumers with accurate information about products that affect their health and that no product affects consumers' health more than cigarettes. Finally, one comment stated that requiring warnings for cigarettes is well established legally and that the addition of graphic images to the warnings represents a difference in form that will not change the fundamental message content of the warnings. As a result, the comment concluded that there is no constitutional basis to delay the implementation of the warning requirements.

(Response) We have carefully considered these comments and we disagree that the warning requirements violate the First Amendment under either of the theories set forth in the comments. To the extent that the warning requirements compel commercial speech, they are permissible under *Zauderer* v. *Office of Disciplinary Counsel of Supreme Court of Ohio,* 471 U.S. 626 (1985), and to the extent that they restrict commercial speech, they satisfy the *Central Hudson* requirements.

The Warning Requirements Permissibly Compel Disclosure of Factual Information. The comments do not dispute that required warnings and other disclosure requirements ''trench much more narrowly on an advertiser's interests than do flat prohibitions on speech'' and may appropriately be required ''in order to dissipate the possibility of consumer confusion or deception'' (*Zauderer,* 471 U.S. at 651 (citation omitted)). Accordingly, regulations that compel ''purely factual and uncontroversial'' commercial speech are subject to more lenient review than regulations that restrict accurate commercial speech and will be sustained if they are ''reasonably related'' to the government's asserted interest (*Id.; see also Milavetz, Gallop & Milavetz, P.A.* v. *United States,* 130 S. Ct. 1324, 1339 (2010) (disclosure requirements are subject to ''less exacting scrutiny'' than affirmative limitations on speech)). ''Commercial disclosure requirements are treated differently from restrictions on commercial speech because mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests'' (*Nat'l Electric Manufacturers Ass'n* v. *Sorrell,* 272 F.3d 104, 113–14 (2d Cir. 2001), *cert. denied,* 536 U.S. 905 (2002)). Instead, such disclosure advances ''the First Amendment goal of the discovery of truth and contributes to the efficiency of the 'marketplace of ideas' '' (*Id.* at 114). ''Protection of the robust and free flow of accurate information is the principal First Amendment justification for protecting commercial speech'' (*Id.*).

The nine new health warning statements and the accompanying graphic images selected by FDA convey information that is factual and uncontroversial. Therefore, the warning requirements are subject to the ''reasonable relationship'' test in *Zauderer,* rather than strict scrutiny as suggested by some of the comments.

The comments do not dispute that the warning statements are true. Indeed, as detailed in the NPRM and in section II.A.2 of this final rule, there is substantial scientific evidence to support the information conveyed in the new required warnings. The NPRM summarizes a large body of scientific evidence showing that cigarettes cause a wide range of negative health consequences, including various types of cancer; all the major cardiovascular diseases, including heart disease and stroke; COPD and other respiratory diseases; and a variety of negative health effects in infants born to women who smoke and in nonsmokers exposed to secondhand smoke (75 FR 69524 at 69527 through 69529). The NPRM also sets forth scientific evidence describing the negative effects of nicotine addiction and the major and immediate health benefits of smoking cessation (75 FR 69524 at 69528 through 69529). As the court in *Commonwealth Brands* correctly observed, the content of the warnings ''is objective and has not been controversial for many decades'' (*Commonwealth Brands,* 678 F. Supp. 2d at 531).

The images we have selected to accompany the nine warning statements also convey information that is factual and uncontroversial regarding the negative health consequences of smoking. These images are consistent with the information conveyed in the

accompanying textual warning statements; each image depicts themes and subjects that provide visual context for the textual warning statements. The images also play a crucial role in the communication of the textual warning information; as discussed extensively in the NPRM, the addition of graphic images to health warning messages causes consumers to notice and attend to the warning information in the first instance, and increases recall of the warning message and the depth of cognitive processing of the message (75 FR 69524 at 69531).

The comments did not dispute that the images proposed to accompany the warning statements accurately depict the negative health consequences of smoking. Rather, they faulted our proposed images for being ''disturbing'' or eliciting emotions. For example, one of the comments cited as disturbing several of the images selected by FDA in this rule, including the images entitled ''hole in throat,'' depicting a man smoking through a tracheostomy opening; ''healthy/diseased lungs,'' depicting healthy lungs juxtaposed with lungs damaged by smoking; ''cancerous lesion on lip,'' depicting a lesion consistent with that caused by oral cancer; and ''man with chest staples,'' depicting a man with an autopsy scar. The comment did not assert, however, that the effects shown in the images are false, *i.e.,* that they are not manifestations of negative health consequences of smoking, such as throat, lung, and oral cancer, and death. The fact that the images are disturbing or evoke emotion does not mean that they are not factual representations of the effects of smoking. In fact, the severe, life-threatening and sometimes disfiguring health effects of smoking conveyed in the required warnings *are* disturbing and the images we have selected appropriately reflect this fact. As such, it is not surprising that the warnings regarding the negative health consequences of smoking would evoke emotions such as fear of being stricken with life-threatening cancer or disgust at what it might be like to have that happen. If the required warnings failed to elicit emotional reactions, they would also fail to communicate the described negative health consequences of smoking in a truthful, forthright manner.

Some comments also stated that ''non-factual cartoon images'' proposed by FDA remove any doubt that the proposed warnings convey an ideological message. For this final rule, one of the images we have selected is, indeed, a graphic illustration. That image shows a ''baby in incubator'' and accompanies the warning statement, ''Smoking during pregnancy can harm your baby.'' As set forth in the NPRM, there is ample evidence to show that smoking during pregnancy has negative effects, including increasing rates of preterm delivery and shortened gestation and increasing the likelihood of low birth weight infants, among other things (75 FR 69524 at 69528). Thus, the image ''baby in incubator'' accurately depicts the health consequences smoking during pregnancy can have for infants born to mothers who smoke. The style of the depiction—here, a graphic illustration—does not make it less factual. The style is just a means to convey the information.

The remaining images we have selected also factually depict the negative health consequences of smoking when viewed in context with their accompanying warning statements. As explained in section III of this document, the image ''smoke approaching baby'' accompanying the statement ''WARNING: Tobacco smoke can harm your children'' effectively conveys the factual message that exposure to tobacco smoke is harmful for children by realistically showing a baby being exposed to secondhand smoke. The image ''oxygen mask on man's face,'' which accompanies the statement ''WARNING: Cigarettes cause strokes and heart disease,'' accurately depicts a typical intervention for a patient suffering acute cardiac distress or stroke. The image ''woman crying,'' which is paired with the statement ''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers,'' is a realistic portrayal of the emotional suffering experienced as a result of disease caused by secondhand smoke exposure. Finally, the image ''man I Quit t-shirt,'' which is paired with the statement ''WARNING: Quitting smoking now greatly reduces serious risks to your health,'' realistically portrays an image of a man that is consistent with and supportive of this factual warning statement, although, unlike the other required warnings, this warning is framed in a positive manner (*i.e.,* it conveys factual information about the negative health consequences of smoking by educating consumers about the positive health consequences of refraining from smoking).

The comments also asserted that some of the proposed images, including some now selected by FDA in this final rule, appear to use technologically-enhanced photographs to emphasize the effects of sickness and disease. While we acknowledge that some of the photographs were technologically modified to depict the negative health consequences of smoking, the effects shown in the photographs are, in fact, accurate depictions of the effects of sickness and disease caused by smoking, and the comments did not dispute this fact.

As one of the comments noted, the addition of graphics to warnings for cigarettes is a difference in form only and does not change the fundamental content of the messages, which convey factual information about the health consequences of smoking. The court in *Commonwealth Brands* was correct when it stated that it ''does not believe that the addition of a graphic image will alter the substance of such [warning] messages, at least as a general rule'' (*Commonwealth Brands,* 678 F. Supp. 2d at 532). Rather, these images alter the effectiveness of the warnings by enhancing their ability to communicate factual information to consumers.

Despite the factual nature of the messages conveyed by the required warnings as described previously, some comments asserted that the government's goal is to force cigarette companies to stigmatize their products by including the government's ideological, antismoking message on their packages and advertisements. These comments claimed that the size of the warnings and the FDA study endpoints assessing consumers' emotional and cognitive reactions to the required warnings and whether the warnings were ''difficult to look at,'' belie any suggestion that they are purely factual.

We disagree with these comments. The size of the warnings and their ability to evoke cognitive and emotional responses are consistent with the government's interest in ensuring that the required warnings effectively communicate factual information about the negative health consequences of smoking to consumers. The NPRM (75 FR 69524 at 69531 through 69534) and section II.D of this final rule summarize the significant research literature supporting FDA's conclusion that larger, graphic warnings more effectively communicate health risks to consumers than the existing smaller, text-only warnings on cigarette packages and in advertisements.

Likewise, our decision to use images that elicit strong cognitive and emotional responses is consistent with established models of risk communication. Our research study included three measures to assess the salience (*i.e.,* noticeability and readability) of the proposed required warnings: Emotional reactions, cognitive reactions, and whether the warning was difficult to look at. Use of

these measures is well-established in the scientific literature. As discussed in the study report (Ref. 49, study report) and in comments discussed in section III of this document, risk information is most readily conveyed by warnings that elicit strong responses on these measures—eliciting strong emotional and cognitive reactions to graphic warnings enhances recall and information processing, which helps to ensure that the warnings are better understood and remembered. These responses in turn influence short-term outcomes, such as later recall of the message and changes in knowledge, attitudes, and beliefs related to the dangers of tobacco use and exposure to secondhand smoke, and eventually lead to long-term changes in behavior. Thus, contrary to the comments discussed previously, our use of these reaction measurements does not demonstrate the Agency's intent to stigmatize tobacco products. Rather, these measures are appropriate indicators of how effectively health warning messages are communicated, and were used in FDA's research study to provide valuable information regarding the relative ability of the 36 proposed required warnings to effectively convey the very real adverse health consequences of smoking to the public.

Indeed, the court in *Commonwealth Brands* rejected an argument that the purpose of the new, larger warnings with their graphic image component is to ''browbeat potential tobacco consumers'' with the government's antismoking message. The court stated that ''the government's goal is not to stigmatize the use of tobacco products on the industry's dime; it is to ensure that the health risk message is actually *seen* by consumers in the first instance'' (*Commonwealth Brands,* 678 F. Supp. 2d at 530 (emphasis in original)). We agree with these findings of the district court.

Because the warning requirements compel the disclosure of information that is purely factual and noncontroversial, they are permissible under *Zauderer* if they are reasonably related to the government's asserted interest. As stated repeatedly in the NPRM and this rule (*see, e.g.,* section II.D of this document), the Agency's primary interest is to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements, a necessary part of which, as the court in *Commonwealth Brands* recognized, is ''to ensure that the health risk message is actually *seen* by consumers in the first instance.'' The warning requirements are clearly reasonably related to this interest.

Both the research literature and FDA's study of the proposed required warnings indicate that the required warnings are effective at communicating the health consequences of smoking to consumers. We have cited extensive literature in the NPRM and in section II.D of this final rule discussing the greater effectiveness of larger, graphic warnings over the current warnings at getting consumers' attention (*see* 75 FR 69524 at 69531 through 69532). For example, in one study in which students were shown images of the Canadian graphic warnings and the current warnings in use in the United States, the Canadian graphic warnings significantly increased aided recall of the warnings, increased depth of message processing, and increased the perceived strength of the message (75 FR 69524 at 69531, *citing* Ref. 97). In addition, as discussed in section III of this document, FDA's study report (Ref. 49) demonstrates that eight of the nine required warnings selected for the final rule showed highly significant effects relative to the text-only control on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) across all of the target audiences (youth, young adults, and adults). The ninth warning, which communicates the message that ''Quitting smoking now greatly reduces serious risks to your health,'' also showed strong effects relative to the text-only control, with significant effects in at least some audiences on the emotional and cognitive reaction scales. Again, these results with respect to the salience measures are important because they have been shown to enhance recall and information processing, which helps to ensure that warnings are better understood and remembered.

As set forth previously, to the extent that the warning requirements compel speech, they are permissible under *Zauderer* because they require disclosure of factual information and are reasonably related to FDA's goal of effectively communicating the health consequences of smoking to consumers. Accordingly, it is not necessary to address the strict scrutiny analyses set forth in the comments.

We are not persuaded to the contrary by the comments' assertions that the warning requirements are unjustified and unduly burdensome. The industry comments discussed previously contended that the warnings are unjustified because the health risks of smoking are already universally known and overestimated and the FDA study results show that the required warnings will have no impact on smoking beliefs or behavior. To support their argument, they cite *Ibanez* v. *Florida Department of Business and Professional Regulation,* 512 U.S. 136 (1994), and *International Dairy Foods Ass'n* v. *Boggs,* 622 F.3d 628 (6th Cir. 2010), for the proposition that courts have found disclosure requirements to be unjustified where the possibility that disclosure will prevent consumer confusion is only speculative.

We disagree with these comments. As discussed in section II.C of this document, there is significant evidence to show that consumers lack knowledge about or underestimate the health risks of smoking. Examples of such evidence include: A 2007 survey that found that two in three smokers underestimate the chance of developing lung cancer; several studies in which only a minority of smokers surveyed believed that they were at increased risk for cancer and heart disease; various studies indicating that Americans who are aware of certain risks, such as cancer, are unaware of the many other health risks associated with smoking; surveys showing that young adults do not appreciate the addictive nature of cigarettes; studies showing that knowledge of smoking risks is even lower among certain demographic groups, such as people with lower incomes and fewer years of education; and research demonstrating that Americans grossly underestimate the effects of secondhand smoke on nonsmokers (*see* section II.C of this document for more extensive discussion of this research).

In addition, we included in the NPRM an extensive discussion of how the current cigarette warnings have gone unnoticed and fail to appropriately convey crucial information to consumers about the health risks of smoking (75 FR 69524 at 69525 and 69529 through 69531). For example, in 1994, the Surgeon General reported that the current warnings, which have been required on cigarette packages and in cigarette advertisements for many years, are given little attention or consideration by viewers (75 FR 69524 at 69525). The same report found that warnings on billboard advertisements were so small that passing motorists could read them only with ''great difficulty'' (*see also* the discussion of billboard advertisements at 75 FR 69524 at 69525). Likewise, as noted in section I.A of this document, a major study into tobacco policy in the United States by the IOM in 2007 concluded that U.S. package warnings are both ''unnoticed and stale'' and found that they fail to communicate relevant information in an effective way (Ref. 3 at 291). The Chair of the IOM's Committee on Reducing Tobacco Use described the warnings on cigarette packs as ''invisible'' in

testimony in 2007 on a precursor to what was enacted as the Tobacco Control Act (75 FR 69524 at 69530). Research regarding warning statements in cigarette advertisements has shown similar results (*Id.,* and studies cited therein). As discussed in the NPRM, the IOM expressed concern about the ability of consumers with less education to recall the information included in text-based messages. The IOM further explained that smokers are more likely to recall larger warnings as well as warnings that appear on the front of packages instead of the side, as is the case for the current warnings (75 FR 69524 at 69531). As the court in *Commonwealth Brands* likewise concluded, the evidence before Congress clearly demonstrates that the new warning requirements are justified (678 F. Supp. 2d at 530–31).

Substantial evidence showing consumer ignorance regarding the health risks of smoking and the ineffectiveness of the current warnings at communicating such risks clearly supports the need for the required warnings. The results of our research study showing significant effects on salience measures for all of the required warnings, along with the substantial international evidence showing that larger, graphic warnings effectively communicate health risks, demonstrate that, unlike the disclosures in the cases cited in the comments, the required warnings will have more than a speculative effect on consumer confusion about the risks of smoking.[7]

Equally unavailing is the assertion that the warning requirements are unduly burdensome because the required size and positioning of warnings on packages and in advertisements effectively rule out tobacco companies' own attempts to convey information. Because this part of the compelled speech argument overlaps with the assertion that the warning requirements restrict speech in violation of the First Amendment, it is addressed in the following paragraphs.

The Warning Requirements Are Permissible Under Central Hudson. To the extent that the challenged provisions restrict commercial speech, the restrictions are analyzed under the framework established in *Central Hudson Gas & Electric Corp.* v. *Public Service Commission,* 447 U.S. 557 (1980). ''The First Amendment's concern for commercial speech is based on the informational function of advertising'' (*Id.* at 563). Consequently, there is no protection for ''commercial messages that do not accurately inform the public about lawful activity'' or that are ''related to illegal activity'' (*Id.* at 563–64). If the communication is neither misleading nor related to unlawful activity, the government may impose restrictions that directly advance a substantial government interest and are not more extensive than is necessary to serve that interest (*Id.* at 566). That standard does not require the legislature to employ ''the least restrictive means'' of regulation or to achieve a perfect fit between means and ends (*Board of Trustees* v. *Fox,* 492 U.S. 469, 480 (1989)). It is sufficient that the legislature achieve a ''reasonable'' fit by adopting regulations '''in proportion to the interest served''' (*Id., quoting In re R.M.J.,* 455 U.S. 191, 203 (1982); *accord Pagan* v. *Fruchey,* 492 F.3d 766, 771 (6th Cir. 2007) (en banc)).

The Supreme Court has emphasized that ''[t]he Constitution gives to Congress the role of weighing conflicting evidence in the legislative process'' (*Turner Broadcasting System, Inc.* v. *FCC,* 520 U.S. 180, 199 (1997)). ''Even in the realm of First Amendment questions where Congress must base its conclusions upon substantial evidence, deference must be accorded to its findings as to the harm to be avoided and to the remedial measures adopted for that end, lest [a court] infringe on traditional legislative authority to make predictive judgments when enacting nationwide regulatory policy'' (*Id.* at 196). Thus, ''the question is not whether Congress, as an objective matter, was correct'' in its determinations (*Id.* at 211). ''Rather, the question is whether the legislative conclusion was reasonable and supported by substantial evidence in the record before Congress'' (*Id.*).

Comments from tobacco product manufacturers argued that the warning requirements restrict tobacco companies' speech because the warnings must occupy the top 50 percent of the front and back display panels of cigarette packages and 20 percent of the area of cigarette advertisements. They stated that these size and positioning requirements are unduly burdensome and will significantly impair their ability to convey information about their products to adult consumers. In essence, their argument is that the new warnings are too large and too prominent, which, as recognized by some of the comments discussed previously, has already been rejected by the court in *Commonwealth Brands* (*see Commonwealth Brands,* 678 F. Supp. 2d at 531).

It is important to note that the comments did not identify *any* specific statements that will be restricted by the warning requirements. Nonetheless, we will assume for the purpose of argument that any speech that possibly could be restricted as a result of this rule would be nonmisleading and relate to lawful activity and, thus, would be commercial speech protected by the First Amendment.

The comments did not dispute that the government has a substantial interest in effectively communicating the health risks of smoking to the public or, as the court in *Commonwealth Brands* characterized it, in ''ensur[ing] that the health risk message is actually *seen* by consumers in the first instance'' (*Id.* at 530). This substantial interest satisfies the first step of the *Central Hudson* analysis.

With respect to the second step, we have repeatedly discussed in the NPRM and this final rule evidence demonstrating that the required warnings will directly advance that interest. Such evidence includes the FDA study results showing significant effects on salience measures for all of the nine required warnings (*see* section III of this document) and the international experience demonstrating the enhanced communication value of larger, graphic warnings (*see* 75 FR 69524 at 69531 through 69533). It also

[7] In *Zauderer,* the asserted government interest was preventing consumers from being misled by a legal advertisement, and thus, the Court noted that warnings or disclaimers could be appropriately required ''in order to dissipate the possibility of consumer confusion or deception'' (*Zauderer,* 471 U.S. at 651 (citations omitted)). In articulating the applicable level of First Amendment scrutiny for disclosure requirements, the Court stated that such requirements must be ''reasonably related to the State's interest in preventing deception of consumers'' (*Id.*). However, appellate courts have held that *Zauderer*'s holding was not limited to disclosure requirements that addressed potentially deceptive advertising, but rather applied to disclosures aimed at better informing consumers about the products that they purchase (*see Sorrell,* 272 F.3d at 115 (applying the *Zauderer* standard and upholding a disclosure statute aimed at increasing consumer awareness of the presence of mercury in various products because the statute's goal was consistent with the policies underlying First Amendment protection of commercial speech and the distinction between compelled and restricted commercial speech); *see also New York State Restaurant Assoc.* v. *New York City Board of Health,* 556 F.3d 114, 133–36 (2d Cir. 2009) (upholding under *Zauderer* a requirement that restaurants disclose calorie content on menus because it was reasonably related to the city's goal of reducing obesity); *Pharm. Care Mgmt. Ass'n* v. *Rowe,* 429 F. 3d 294, 310 n. 8 (1st Cir. 2005) (stating that the court did not find any cases limiting *Zauderer* to ''potentially deceptive advertising directed at consumers'')).

Thus, even if there were no consumer confusion regarding the health risks of smoking that needed to be addressed by the required warnings, the government would still have an interest in updating the warnings and better informing consumers about the effects of the products that they purchase—particularly products such as cigarettes, which have such a significant impact on health. Accordingly, the *Zauderer* standard would still apply.

includes studies showing the improved effectiveness of Canada's larger, graphic warnings at communicating health risks. For example, national surveys conducted on behalf of Health Canada indicate that approximately 95 percent of youth smokers and 75 percent of adult smokers report that the Canadian pictorial warnings have been effective in providing them with important health information (*see* Ref. 3 at p. 294). In another study of adult smokers, more than half of the study participants reported that the pictorial warnings made them think about the health risks of smoking (Ref. 44). A study comparing Canadian and United States warnings found that while ''83 percent of Canadian students mentioned health warnings in a recall test of cigarette packages,'' only ''7 percent of U.S. students'' did the same (*see* Ref. 3 at C–3 to C–4).

The comments that argued that the warning requirements are unconstitutionally restrictive ignored this evidence. Instead, they suggested that, to satisfy this step, FDA's research study would have to have shown a material impact on consumers' beliefs about, or understanding of, the health risks of smoking or smoking behavior.

We disagree. The evidence showing that the required warnings will directly advance the government's primary goal of effectively communicating the negative health consequences of smoking by first ensuring that the warnings will be seen and processed by consumers is sufficient to satisfy the second step of *Central Hudson.* A showing with respect to other goals, such as impacts on consumer beliefs or smoking behavior, is not necessary for purpose of this analysis. However, we note that there is significant evidence that these goals will also be advanced by the warning requirements.

The comments repeatedly cited to FDA's study report to support the proposition that the required warnings will have no effect on consumer beliefs or behavior. However, such an assertion fails to take into account the study design and the extensive evidence in the literature indicating that the required warnings will positively impact beliefs and behavior. As we note in section III of this document, it is not surprising that the proposed required warnings, as a whole, did not elicit strong responses on the beliefs and intentions measures because study participants had only a single exposure to one warning; the study was not designed to show long-term effects on behavior. However, the study cannot be viewed in isolation from the overall body of scientific evidence regarding the positive effects of larger, graphic health warnings on smoking beliefs and behavior, which we summarized in the NPRM (75 FR 69524 at 69531 through 69534).

Finally, the comments stated that the warning requirements do not satisfy the third step of the *Central Hudson* test because the mandated size and positioning of the warnings on packages and advertisements will effectively rule out tobacco companies' ability to convey information about their products. They stated that the requirements are more extensive than necessary to achieve the government's interests and suggested that less-speech restrictive alternatives, including alternatives to the warning size and positioning requirements included by Congress in the Tobacco Control Act, would be equally as effective.

The comments provided no basis for setting aside Congress' judgment as to the appropriate specifications. As the court in *Commonwealth Brands* explained, Congress considered extensive evidence, starting with the 1994 Surgeon General's Report and ending with the 2007 IOM Report, which is discussed in the NPRM (75 FR 69524 at 69530), demonstrating that the existing warnings are ''unnoticed'' and ''stale'' and decided that the content and format of the warnings needed to be revised (*Commonwealth Brands,* 678 F. Supp. 2d at 530–31). In so doing, Congress chose specifications for the warnings that accord with FCTC, which calls for warnings that ''shall be rotating,'' ''shall be large, clear, visible and legible,'' ''should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas,'' and ''may be in the form of or include pictures or pictograms'' (FCTC art. 11.1(b)). The FCTC has been signed by the United States and ratified by 167 countries. As the *Commonwealth Brands* court correctly found, ''Congress also informed its warning requirements by looking at the use of a nearly identical warning requirement in Canada'' (*Commonwealth Brands,* 678 F. Supp. 2d at 531). Like the required warnings, the Canadian warnings occupy the top half of the two main panels of cigarette packages.

Thus, Congress based its legislative decision to revise the warnings in the first instance and to mandate certain size and placement specifications for the warnings on substantial evidence in the record. At this time, we do not intend to change those specifications. Although comments from tobacco companies asserted that the larger size leaves inadequate room for their own commercial messages, they identified no information that is suppressed by virtue of the larger warnings, even though they have complied with similar requirements in other countries for years. The tobacco companies retain more than half of their cigarette packaging and 80 percent of their advertisements for their own commercial speech.

Moreover, extensive disclosure requirements are by no means unique to cigarettes. For example, for products such as pain relievers, certain allergy medications, and products to treat a variety of cold symptoms, the required warnings together with other FDA-required information typically encompass more than 50 percent of the product packaging.[8]

For these reasons, ''the warning requirement is sufficiently tailored to advance the government's substantial interest under *Central Hudson''* (*Id.* at 532).

The reliance by two comments on the Seventh Circuit's decision in *Entertainment Software Association* v. *Blagojevich,* 469 F.3d 641 (7th Cir. 2006), does not persuade us to the contrary. In that case, the court invalidated a State law requiring video-game retailers to place a four-square-inch label with the numerals ''18'' on any ''sexually explicit'' video game. Unlike here, the court concluded that the sticker ''communicates a subjective and highly controversial message—that the game's content is sexually explicit,'' a term capable of multiple definitions, and expressly rejected the comparison to the ''surgeon general's warning of the carcinogenic properties of cigarettes, the analogy the State attempts to draw'' (*Id.* at 652). ''Applying strict scrutiny,'' the court noted that ''[t]he State has failed to even explain why a smaller sticker would not suffice'' (*Id.*). Here, by contrast, Congress has required accurate and objective warnings in a format that accords with the provisions of the FCTC, to which the United States is a signatory, and whose effectiveness has been demonstrated by international experience, after concluding existing, yet smaller, warnings were ineffective at conveying important health information.

We also disagree with the assertion in the comments that the warning requirements fail to meet the third step of *Central Hudson* because the government failed to consider numerous less speech-restrictive alternatives. One of the comments suggested that the government disseminate information

[8] See 21 CFR 201.66; see also *http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022032s003lbl.pdf* (example of packaging for OTC heartburn medication).

about health risks as one alternative for communicating health risks to consumers. However, government dissemination of the message already occurs—for example, HHS currently has several hundred tobacco-related Web sites, which provide informative messages regarding, for example, the harmful effects of tobacco use (Ref. 89), and CDC's Office on Smoking and Health funds health departments in all 50 states, the District of Columbia, and seven U.S. territories for comprehensive tobacco prevention and control and provides access to tobacco control advertising material for use in this comprehensive effort (*see* Ref. 98). However, as discussed in section II.C of this document, evidence shows that the health risks are still misunderstood or underestimated by consumers. Moreover, government advertising cannot take the place of displaying effective warnings on product packaging, which ''can provide a clear, visible vehicle to communicate risk at the most crucial time for smokers and potential smokers''—the very instant that they are deciding whether to purchase or consume a cigarette (75 FR 69524 at 69529). Indeed, ''[p]ack-a-day smokers are potentially exposed to warnings more than 7,000 times per year'' (*Id.;* Refs. 11, 99, and 100).

To the extent that the comments discussed other suggested alternatives (*e.g.,* increased enforcement of sales to minors, increased funding for tobacco control programs, increased taxes) in the context of their ability to reduce youth smoking, the suggestions provided are misplaced in an analysis of requirements whose primary purpose is effective communication of health risks. These suggested alternatives were not aimed at communicating health risks and were not effective at doing so. In any event, *all* of these alternatives have been implemented by the government in one form or another and have been insufficient. This is reflected in the findings of the *Commonwealth Brands* court:

> Plaintiffs' argument is premised on the idea that ''[b]efore a government may resort to suppressing speech to address a policy problem, it must show that regulating conduct has not done the trick or that as a matter of common sense it could not do the trick.'' (Plaintiffs' Brief, p. 26) (quoting *BellSouth,* 542 F.3d at 508); see also *Western States,* 535 U.S. at 373. However, that is precisely what Congress has done here. Contrary to Plaintiffs' contention, this is not a case where Congress went ''straight to [their] speech.'' (Plaintiffs' Brief, p. 19). This is a case where Congress, after decades of implementing various measures that did not affect Plaintiffs' speech, decided to add label and advertising restrictions to its comprehensive regulation of the tobacco industry. That decision seems eminently reasonable, too, since every other tool in the government's arsenal is made less effective and more costly by Plaintiffs' use of advertising ''to stimulate underage demand.'' (Government's Response, p. 40). Accordingly, the Court rejects Plaintiffs' contention that the existence of ''numerous obvious non-speech-restrictive alternatives'' renders the Act's speech restrictions unconstitutional for lack of tailoring. (678 F. Supp. 2d at 538).

For all of the reasons set forth in the previous paragraphs, we conclude that the warning requirements do not violate the First Amendment.

(Comment 200) One tobacco industry comment also claimed that requiring a reference to a cessation resource in the required warnings would violate the First Amendment because it is compelled speech that does not convey factual information about the product that is being sold. This comment claimed that requiring a cessation resource communicates a subjective policy message that consumers should not buy or use the product.

(Response) We disagree. As explained previously, the requirement in this rule for graphic warnings on cigarette packages and advertisements is consistent with the First Amendment. Contrary to the comment, the reference to a cessation resource, when considered in context with the rest of the required warnings, conveys factual information to consumers and is permissible under the *Zauderer* standard for compelled disclosures because it is reasonably related to our interest in increasing the likelihood that existing smokers will become aware of the cessation resource and, consequently, increasing the likelihood that those who want to quit will be successful. It is also reasonably related to our interest in effectively communicating the health risks of smoking to consumers.

As discussed in detail in section V.B.6 of this document, the rule requires each required warning to include a reference to the existing National Network of Tobacco Cessation Quitlines (Network), which uses the telephone portal 1–800–QUIT–NOW. This rule will require that the cessation resource be displayed on the required warning images: ''1–800–QUIT–NOW''.

The NPRM cited evidence that more than 70 percent of smokers in the United States report that they want to quit, and approximately 44 percent report that they try to quit each year (75 FR 69524 at 69529; Ref. 66 at p. 15). However, as a result of nicotine addiction, only a very small percentage of these smokers achieve success (75 FR 69524 at 69528 through 69529).

Instead of advocating a subjective policy message as suggested by the comment, including a cessation resource on required warnings will provide factual information for the many smokers who have already developed a desire to quit, either prior to or after viewing the health risk information in the required warnings. The reference is designed to inform such smokers and others that a resource exists that can help smokers to quit and to inform them how they can access that resource. The factual nature of this information is underscored by our explanation in the NPRM that the Agency's goal is ''to provide a place where smokers and other members of the public can obtain smoking cessation information from staff trained specifically to help smokers quit by delivering *unbiased and evidence-based information, advice, and support''* (75 FR 69524 at 69540 (emphasis added)). In addition, our adoption of detailed criteria designed to ensure that the resource's information, advice, and support are unbiased and evidence-based further emphasizes that the required reference to a cessation resource is factual in nature.

We disagree that a reference to a cessation resource does not convey information about the product being sold. The reference must be considered in context with the rest of the required warnings, which consist of textual statements and accompanying graphic images conveying to consumers factual information regarding the negative health consequences of smoking and the benefits of quitting. The reference to a smoking cessation resource naturally complements this information; instead of leaving consumers who are motivated to quit by the health risk information unassisted, it provides them with a concrete step to take action on this information.

Because the reference to a smoking cessation resource conveys factual information, it is permissible under *Zauderer* if it is reasonably related to the government's asserted interest. Here, the reference is reasonably related to FDA's interest in increasing the likelihood that existing smokers will become aware of the cessation resource and, consequently, increasing the likelihood that they will successfully quit smoking. As set forth in the discussion of the comments in section V.B.6 of this document, foreign countries that have included cessation resources on cigarette package warnings have generally experienced large increases in volume of calls to quitlines following their appearance on cigarette packages. In addition, as also discussed

in section V.B.6 of this document, the effectiveness of telephone quitlines is well documented; there is evidence that significant numbers of smokers are unaware of such assistance, even after extensive media campaigns; and there is evidence that knowing about the availability of a quitline increases quit attempts and successful cessation even among smokers who do not call the quitline.

Moreover, requiring a smoking cessation resource is also reasonably related to FDA's interest in effectively communicating the health risks of smoking to consumers. As noted in the NPRM (75 FR 69524 at 69541) and in section V.B.6 of this final rule, there is evidence to show that including a reference to a smoking cessation resource in graphic warnings can enhance the effectiveness of graphic warnings at conveying health risk information to the public. We have determined that it is also important to inform smokers about a specific tool they can use to help them to quit smoking at the time they are looking at the warnings and thinking about the health consequences of smoking and the positive health benefits of quitting. Risk communication research indicates that messages that arouse fear about the health risks of smoking should be combined with information on concrete steps that can be taken to reduce those risks (Ref. 81 (Messages that arouse fear ''appear to be effective when they depict a significant and relevant threat * * * and when they outline effective responses that appear easy to accomplish * * *.'')). As one comment stated, providing information about how to reduce a risk that arouses fear helps to prevent consumers from suppressing thoughts about such risks, and thereby, failing to process the risk information. For this reason, too, we do not agree that the requirement to refer to a smoking cessation resource on cigarette packages and advertisements violates the First Amendment.

C. Takings Under the Fifth Amendment

We received a comment related to the Takings Clause of the Fifth Amendment. That comment is summarized and responded to in the following paragraphs.

(Comment 201) One comment submitted by several tobacco companies argued that the new health warning requirements unconstitutionally deprive them of their property rights in violation of the Takings Clause of the Fifth Amendment. The tobacco companies asserted that the new required warnings constitute a *per se* physical taking of their packaging and advertising space, as well as a regulatory taking of their property interests in their trademarks.

(Response) We disagree that the rule effects a taking under either theory. The Takings Clause provides that ''private property [shall not] be taken for public use, without just compensation.'' A takings analysis begins with a threshold determination of what interest a person has in the thing that is allegedly taken (*see Ruckelshaus* v. *Monsanto Co.,* 467 U.S. 986, 1001 (1984)). In order to assert a taking, a person must first identify a specific, concrete property interest that has been invaded or destroyed by the government (*Penn Central Transp. Co.* v. *New York City,* 438 U.S. 104, 124–25 (1978)). Once a concrete property interest is identified, it is necessary to determine whether the government's action constitutes a taking of that interest.

The graphic warning requirements do not effect a *per se* taking. To conclude that a categorical, or *per se,* taking has occurred when the government directly appropriates or physically invades property is another way of saying that the government action so onerously burdens an important property right that the inquiry ends there. As the Supreme Court has explained: ''A permanent physical invasion, however minimal the economic cost it entails, eviscerates the owner's right to exclude others from entering and using her property—perhaps the most fundamental of all property interests'' (*Lingle* v. *Chevron U.S.A. Inc.,* 544 U.S. 528, 539 (2005); *see also Loretto* v. *Teleprompter Manhattan CATV Corp.,* 458 U.S. 419, 433 (1982) (citation omitted) (''[T]he land-owner's right to exclude [is] 'one of the most essential sticks in the bundle of rights that are commonly characterized as property.' '')).

Viewed in this light, a requirement that tobacco companies display graphic health warnings as part of the package label on their products cannot be equivalent to the ''physical invasion'' of real property in the cases that the comment cites to support its *per se* takings argument (*see Loretto,* 458 U.S. at 441 (''Our holding today is very narrow.'')). The warnings involve personal property of a type that is already subject to extensive government regulation. Indeed, given the ubiquitous nature of government-mandated warnings on all kinds of consumer products, manufacturers of inherently dangerous products such as cigarettes cannot be said to have a categorical right to exclude health warnings from their products' labels.[9] Therefore, the tobacco companies have failed to identify the sort of property right the destruction of which would result in a *per se* taking.

Furthermore, as the Supreme Court has explained, the Takings Clause exists ''to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole'' (*Armstrong* v. *United States,* 364 U.S. 40, 49 (1960); *see Monongahela Nav. Co.* v. *United States,* 148 U.S. 312, 325 (1893)). The tobacco companies' argument amounts to an assertion that they must be compensated because they have been required to allow health warnings on their property. The point of the warnings is to protect the public health by informing consumers about the many harmful effects of the companies' products, which kill an estimated 443,000 Americans every year. Therefore, the proposition that the public must pay for the cost of the warnings on tobacco products is simply not compatible with how ''the burden of common citizenship'' is proportioned in our system of modern government (*see Keystone Bituminous Coal Ass'n* v. *DeBenedictis,* 480 U.S. 470, 488–91 (1987); *Pennsylvania Coal Co.* v. *Mahon,* 260 U.S. 393, 413 (1922) (''Government hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law.'')).

In addition, the graphic warning requirements do not effect a regulatory taking. The tobacco companies also argue that the warnings constitute a regulatory taking because they have a reasonable expectation that their property rights will be protected based on statutory and common law protections provided to trademarks and trade dress. The tobacco companies do not identify the specific statutory or common law protections that led to their expectation that their property would be protected. Also lacking is an explanation of how the rule would interfere with such expectations. In any event, we do not agree that the rule effects a regulatory taking of the tobacco companies' property.

The Supreme Court has declined to prescribe a ''set formula'' for identifying takings and instead has characterized a takings analysis as an ''essentially ad hoc, factual'' inquiry (*Penn Central,* 438 U.S. at 124). Nonetheless, the Court has identified three factors for consideration in assessing whether a regulatory taking has occurred: (1) The character of the

[9] For example, for products such as pain relievers, certain allergy medications, and products to treat a variety of cold symptoms, the required warnings together with other FDA-required information typically encompass more than 50 percent of the product packaging (*see* 21 CFR 201.66).

governmental action; (2) the regulation's economic impact; and (3) the extent to which the regulation interferes with reasonable investment-backed expectations (*Ruckelshaus,* 467 U.S. at 1005). The force of any one of these factors may be ''so overwhelming * * * that it disposes of the taking question'' (*Id.*).

With respect to the first *Penn Central* factor, the character of the government action, the government is ''given the greatest leeway to act without the need to compensate those affected by their actions'' when the government has acted for ''the protection of health and safety'' (*Rose Acre Farms, Inc.* v. *United States,* 559 F.3d 1260, 1281 (Fed. Cir. 2009)). Indeed, the Supreme Court has rejected takings claims arising out of health and safety legislation even where a property interest has been destroyed (*see Penn Central,* 438 U.S. at 125–27 (citing cases)). Thus, as explained previously, this factor of the analysis weighs strongly in favor of finding that no taking will occur as a result of this rule.

The second factor to consider is the economic impact of the government action. The analysis involves looking not just at what has been lost, but at the nature and extent of the interference with rights in the property as a whole (*see Penn Central,* 438 U.S. at 130–31). Thus, it is necessary to assess the impact of the rule on tobacco companies' trademarks, packages, and advertisements as a whole. In assessing whether a regulation effects a taking, the Supreme Court has considered whether the regulation denies an owner the ''economically viable'' use of its property. Mere denial of the most profitable or beneficial use of property does not require a finding that a taking has occurred (*see, e.g., Keystone,* 480 U.S. at 498–99). Here, tobacco companies have not shown how the rule deprives them of the use of their intellectual property or packaging to such a severe extent to effect a taking (*see Village of Euclid* v. *Ambler Realty Co.,* 272 U.S. 365, 384 (1926) (75 percent diminution in value insufficient to prove taking); *Hadacheck* v. *Sebastian,* 239 U.S. 394, 405 (1915) (92.5 percent diminution insufficient to prove taking)). Manufacturers, importers, distributors, and retailers will still be able to use packages and advertisements to sell cigarettes. Indeed, manufacturers still have use of 50 percent of the front and rear panels of cigarette packages, as well as the side panels and the top and bottom panels, to use their trademarks and otherwise promote their products. Eighty percent of the area of each advertisement will likewise be available. Accordingly, the second factor of the analysis also supports the conclusion that no taking will occur as a result of the rule.

The vague suggestion that the rule interferes with tobacco companies' ''reasonable investment-backed expectations'' is similarly unpersuasive. To be reasonable, expectations must take into account the power of the State to regulate in the public interest (*Pace Resources, Inc.* v. *Shrewsbury Township,* 808 F.2d 1023, 1033 (3d Cir.), *cert. denied,* 482 U.S. 906 (1987)). The nature of the property, and whether it has historically been, or potentially could be, subject to regulation also aids in determining whether any expectation in remaining free from regulation is reasonable. ''[I]n the case of personal property, by reason of the State's traditionally high degree of control over commercial dealings, [the property owner] ought to be aware of the possibility that new regulation might even render his property economically worthless * * *.'' (*Lucas* v. *South Carolina Coastal Council,* 505 U.S. 1003, 1027–28 (1992)). This is particularly true with respect to cigarettes, which are lethal and addictive—features the industry masked for decades while stimulating underage demand (*see United States* v. *Philip Morris USA, Inc.,* 566 F.3d 1095, 1124 (DC Cir. 2009); *United States* v. *Philip Morris USA, Inc.,* 449 F. Supp. 2d 1, 580 (Finding 2717) (D.D.C. 2006); Ref. 54 at p. 211). Commerce in tobacco products has been regulated for decades, subject to increasingly more restrictive Federal, State, and local measures over time. Indeed, Congress has mandated warnings on cigarette packs since 1965 (*see* Federal Cigarette Labeling and Advertising Act of 1965 (FCLAA), Pub. L. 89–92, 79 Stat. 282). Congress later amended FCLAA to update the text of the cigarette warnings and mandate them in cigarette advertisements as well (*see* Comprehensive Smoking Education Act of 1984, Pub. L. 98–474, 98 Stat. 2200). In light of this long history of regulation, companies that package and advertise cigarettes lack a reasonable investment-backed expectation that they will be able to continue to use their property without modification of the regulatory requirements that protect the public health. Any expectation that the industry would escape comprehensive regulation, such as the Tobacco Control Act, was eminently unreasonable.

For these reasons, the third factor of the takings analysis, like the first two factors, compels the conclusion that the rule does not amount to a regulatory taking of property that requires compensation under the Fifth Amendment.

VIII. Implementation Date

In the preamble to the proposed rule, FDA stated that the final rule would become effective 15 months after the date the final rule publishes in the **Federal Register**. This time period is consistent with section 201(b) of the Tobacco Control Act, which specifies that the requirements for health warnings on cigarette packages and in advertisements are effective 15 months after the issuance of the regulations that FDA issues in this rulemaking.

In particular, we proposed that as of the effective date, no manufacturer, importer, distributor, or retailer of cigarettes may advertise or cause to be advertised within the United States any cigarette product unless the advertising complies with the final rule. With respect to cigarette packages, we explained that cigarettes must not be manufactured after the effective date unless their packages comply with the regulation. If any packaged cigarette product was manufactured prior to the effective date and does not comply with the final rule, a manufacturer may continue to introduce that package into commerce in the United States for an additional 30 days after the effective date of the final rule. After 30 days following the effective date, a manufacturer may not introduce into domestic commerce any cigarette the package of which does not meet the requirements of the final rule (75 FR 69524 at 69541). We noted that this limitation applied only to manufacturers and requested comments regarding mechanisms for enforcing this rule and its effective date, including ways to differentiate cigarette packages sold from inventory manufactured prior to the effective date rather than from inventory manufactured after the effective date.

We received several comments about the effective date, particularly requesting clarification regarding its application to manufacturers, distributors, and retailers after the 30-day period in which manufacturers may continue to sell noncompliant packages. Based on the comments and our review of the language in section 201(b) of the Tobacco Control Act, we find:

- The effective date should be 15 months after the date of publication in the **Federal Register** of this final rule;
- No manufacturer, importer, distributor, or retailer may advertise any cigarette product after the effective date if the advertisement does not comply with this rule;
- After the effective date, no person may manufacture for sale or distribution within the United States any cigarette

the package of which does not comply with this rule;

- Beginning 30 days after the effective date of this rule, a manufacturer may not introduce into domestic commerce any cigarette, irrespective of the date of manufacture, if its package does not comply with the requirements of this rule;
- After the effective date, an importer, distributor, or retailer may not sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarette the package of which does not comply with this regulation, unless the cigarette was manufactured prior to the effective date; and
- After the effective date, however, a retailer may sell cigarettes the packages of which do not have a required warning if the retailer demonstrates it falls outside the scope of this rule as described in § 1141.1(c).

In the following paragraphs, we describe the individual comments concerning the effective date and respond to these comments.

(Comment 202) Several comments expressed the view that 15 months is an excessive amount of time to allow the tobacco industry before it must comply with the new requirements of this rulemaking. For example, some comments contended that tobacco companies have employed marketing and advertising experts and are continuously changing cigarette packaging and advertisements. These comments also noted that the tobacco industry has known that they will need to update packaging and advertising to comply with this regulation since the passage of the Tobacco Control Act. Some comments estimated the number of Americans that will become new smokers or die due to smoking during the 15 months prior to the effective date. Other comments recognized that the statute specifies a 15-month effective date, but requested that FDA make clear that cigarette packages manufactured after the effective date must comply with the requirements of the regulation.

(Response) The Tobacco Control Act specifies a 15-month implementation period for cigarette manufacturers to include required warnings on their packages and for all cigarette advertisements to comply with this rule. We agree this is an appropriate amount of time for implementation of the rule.

(Comment 203) One tobacco product manufacturer indicated in its comment that all manufacturers should be required to implement the same warning requirements within the same time periods, and that there should not be a separate implementation period for small manufacturers.

(Response) As in the proposed rule, the implementation date in the final rule is the same for all manufacturers, regardless of size.

(Comment 204) One comment requested that FDA delay implementation of the rule until Constitutional issues raised in the comment are resolved either administratively or through litigation.

(Response) We disagree that the effective date of this rule should be delayed beyond the 15 months proposed in the NPRM. As explained in section VII of this document, we disagree that there are any Constitutional deficiencies associated with this rule and, therefore, there is no need to revise the rule or issue a new proposed rule to address these alleged deficiencies. Furthermore, section 201(b) of the Tobacco Control Act specifies that the requirements for health warnings on cigarette packages and in advertisements for cigarettes are effective 15 months after the issuance of this final rule.

(Comment 205) Several comments addressed the 30-day period for manufacturers to sell noncompliant packages that were manufactured prior to the effective date. One comment asserted that it is unnecessary to permit this 30-day sell-off period if there is adequate time for manufacturers to make necessary changes to cigarette packages prior to the effective date. The comment cited the United Kingdom as an example of a jurisdiction where tobacco product manufacturers had adequate lead time (1 year to implement changes to cigarette packages and 2 years to introduce picture warnings on other tobacco products) to meet implementation deadlines so that only compliant packages were sold after the compliance deadline. Other comments recognized that the statute grants manufacturers 30 days to sell noncompliant cigarette packages; however, these comments emphasized that FDA does not have the discretion to lengthen the 30-day period. Comments also stressed that any additional delay of implementation would needlessly delay the important public health benefits of the rule.

(Response) As explained previously, section 201(b) of the Tobacco Control Act specifies that manufacturers have an additional 30 days to sell cigarette packages that do not meet the requirements of the regulation if those packages were manufactured prior to the effective date.

(Comment 206) A small tobacco product manufacturer requested that FDA specify the meaning of the term ''introduce into domestic commerce.'' The comment asked whether the term means out of the manufacturer's possession. The comment raised this question in the context of expressing concern that distributors and retailers might want to return product to a manufacturer if there is doubt about a distributor or retailer being permitted to sell cigarette packages that do not have a required warning, but were introduced intro domestic commerce by the manufacturer during the 30-day sell through period for manufacturers.

(Response) We agree with this comment that when a cigarette package has been sold by the manufacturer and is in the possession of a distributor or retailer, the product would be considered introduced into domestic commerce. However, we do not agree that a definition of ''introduce into domestic commerce'' is needed at this time. The comment recognized that there was similar language in the context of a statutory prohibition on the use of ''light,'' ''low,'' and ''mild'' descriptors and related FDA guidance for industry, however, that guidance did not define the phrase ''introduce into domestic commerce.'' We are not aware of confusion regarding this phrase in the context of ''light,'' ''low,'' and ''mild'' descriptors and decline to define that phrase here.

(Comment 207) Public health advocacy groups expressed concern that manufacturers will seek to sell a disproportionate number of noncompliant cigarette packages immediately prior to the expiration of the 30-day sell-off period and, therefore, FDA should take steps to ensure that all these sales are fully documented. The comment recommended that FDA impose certain requirements for selling noncompliant cigarette packages, such as a requirement to mark these packages with a statement that the product was manufactured prior to September 22, 2012, or with a readily identifiable symbol. This comment also recommended that each manufacturer be required to certify that all cigarettes so marked were manufactured before that date and submit an accounting of the number of packages on hand as of the effective date, the number of cigarette packages introduced into commerce during the 30-day period, and the number of packages on hand as of the expiration of the 30-day period. This comment also suggested that FDA not permit manufacturers to introduce into commerce in any calendar month a number of noncomplying cigarette packages that exceeds 10 percent of the average total number of cigarette packages introduced per month during the preceding year.

(Response) We disagree that such specific requirements are necessary to address a one-time sell-off period of 30 days. We recognize that some manufacturers may try to increase their sales of cigarette packages prior to the effective date and prior to the expiration of the sell-off period. However, there will be some limit to the demand for these cigarette packages. Manufacturers may increase manufacturing prior to the effective date at their own risk. After the 30-day sell-off period, a manufacturer may not sell noncompliant cigarette packages and would need to repackage or destroy any noncompliant cigarettes packages intended to be sold in the United States.

(Comment 208) One comment requested that importers be required to comply with all requirements applicable to manufacturers. According to this comment, importers should be prohibited from introducing noncomplying cigarettes imported after the effective date and should be required to meet the same requirements as manufacturers with respect to cigarettes manufactured prior to the effective date and sold after the effective date.

(Response) This comment did not provide a statutory interpretation that would justify this approach. Section 201(b) of the Tobacco Control Act states the effective date ''shall be with respect to the date of manufacture'' and that 30 days after the effective date, a manufacturer is precluded from introducing into domestic commerce any product that is not in conformance with section 4 of FCLAA. No similar statutory provision applies to importers or distributors.

(Comment 209) Public health advocacy groups requested that FDA clarify that manufacturers are not prohibited from introducing into commerce cigarette packages that comply with the regulation prior to the effective date.

(Response) We agree that manufacturers are not precluded from introducing into commerce cigarette packages that contain required warnings in accordance with the regulation prior to the effective date. We also note that a cigarette manufacturer, importer, or retailer may include a required warning in an advertisement prior to the effective date. However, because the health warning requirements in FCLAA do not change until the effective date of this rule, any manufacturer, importer, or retailer that, prior to the effective date, includes a new required warning on a cigarette package or advertisement must also comply with the warning requirements under the current version of FCLAA and any warning plan approved by the FTC.

(Comment 210) Many comments requested clarification regarding whether there is any limitation on the period during which distributors and retailers may sell cigarettes that were manufactured prior to the effective date that are not compliant with the rule. Several comments submitted by organizations representing manufacturers and retailers asked that FDA clarify that distributors and retailers have an unlimited period to sell cigarette packages that do not comply with the regulation as long as the cigarettes were manufactured prior to the effective date. Several comments noted that this approach would be consistent with FDA's treatment of cigarettes with the descriptors ''light,'' ''low,'' and ''mild.'' One manufacturer commented that any restraint on the ability of distributors or retailers to sell through their lawfully acquired product would unfairly deprive them of the benefit of their investment. Small tobacco product manufacturers noted that small manufacturers cannot afford to have distributors and retailers returning product based on a potential labeling concern. Retailer comments contended that limiting a sell-off period may cause a severe financial burden on small retailers because manufacturers generally do not allow cigarettes to be returned. Retailers also claimed that cigarettes do not have an indefinite shelf life and both distributors and retailers generally turn over their cigarette inventory in a timely manner. One comment suggested that retailers should be allowed to sell noncompliant cigarette packages at least through their ''sell by'' date, as indicated on the cigarette package by the manufacturer.

On the other hand, one comment claimed it is essential that there be a fixed implementation deadline at the retail level or old stock can be expected to remain on retail store shelves for 6 months and more after the effective date.

(Response) As explained in the NPRM, section 201(b) of the Tobacco Control Act describes no limitation on the period during which distributors and retailers may sell cigarette packages that were manufactured prior to the effective date of this rule. In addition, there is no requirement that manufacturers include a ''sell by'' date on all cigarette packages. We note, however, that distributors, importers, and retailers are responsible for complying with this rule. After the rule's effective date, they may not sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarette the package of which does not comply with this regulation, unless the cigarette was manufactured prior to the effective date. After the effective date, however, retailers may sell cigarettes the packages of which do not have a required warning if they demonstrate they meet the provisions of § 1141.1(c) and are exempt from the requirements of 21 CFR part 1141 that apply to the display of health warnings on cigarette packages.

IX. Federalism

FDA has 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.'' This rule is being issued under section 4 of FCLAA, as amended by the Tobacco Control Act, and sections 701(a), 903, and 906 of the FD&C Act (21 U.S.C. 371(a), 387c, and 387f), as amended by the Tobacco Control Act. Federal law includes an express preemption provision that preempts any requirement, except under the Tobacco Control Act, for a ''statement relating to smoking and health, other than the statement required by section 4 of [FCLAA], * * * on any cigarette package.'' (section 5(a) of FCLAA (15 U.S.C. 1334(a))). It also includes an express preemption provision that preempts any ''requirement or prohibition based on smoking and health * * * imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of [FCLAA],'' which includes section 4 of FCLAA (section 5(b) of FCLAA). However, section 5(b) of FCLAA does not preempt any State or local statutes and regulations ''based on smoking and health, that take effect after [June 22, 2009], imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes'' (section 5(c) of FCLAA).

In addition, section 916(a)(2) of the FD&C Act (21 U.S.C. 387p) expressly preempts any State or local requirement ''which is different from, or in addition to, any requirement under [Chapter IX of the FD&C Act] relating to,'' among other things, misbranding and labeling. This express preemption provision, however, ''does not apply to

requirements relating to'' among other things ''the sale, distribution, * * * access to, [or] the advertising and promotion of * * * tobacco products.''

X. Environmental Impact

FDA has determined under § 25.30(k) (21 CFR 25.30(k)) that this action is of a type that does not individually or cumulatively have an impact on the human environment. Therefore, neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required. We received one comment on this issue, which we have summarized and responded to in the following paragraphs.

(Comment 211) One comment expressed concern regarding FDA's statement in the proposed rule that this action does not individually or cumulatively have an impact on the human environment. The comment stated that there is an impact on the environment due to the fact that a reduction in the number of cigarettes consumed will result in a reduction of cigarette-related waste. The comment explained that cigarette butts pose a greater health hazard than most other litter, because they contain toxins that can be leached into water systems. The comment requested that this be included in FDA's analysis to understand the large positive impact the required warnings will have on the human environment.

(Response) We have considered this comment, but have concluded that neither an EA nor an EIS is required under § 25.30(k). We have determined that a categorical exclusion applies in this instance, because (1) the action meets the criteria of the exclusion, *i.e.,* there are no increases in existing levels of use or changes in intended use, and (2) there are no extraordinary circumstances.

According to the National Environmental Policy Act of 1969 (NEPA) and the Agency's corresponding regulations, FDA must prepare an EIS for major Federal actions ''significantly affecting the quality of the human environment'' (*see* 40 CFR 1501.4; 21 CFR 25.22). If the action ''may'' have such a significant environmental effect, an agency must prepare an EA to provide sufficient evidence and analysis for the agency to determine whether to prepare an EIS or a finding of no significant impact (FONSI) (*see* 40 CFR 1501.3; 21 CFR 25.20). Agencies can establish categorical exclusions for categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an EA nor an EIS is required (*see* 40 CFR 1508.4). However, FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that ''the specific proposed action may significantly affect the quality of the human environment'' (*see* 21 CFR 25.21; 40 CFR 1508.4).

A regulation to modify labeling regulations constitutes a major Federal action under NEPA (*see* 40 CFR 1508.18), and typically requires at least an EA under 21 CFR 25.20(f). However, regulations establishing labeling requirements for marketed articles are categorically excluded, if the action will not result in (1) increases in the existing levels of use of the article or (2) changes in the intended use of the article (§ 25.30(k)). Therefore, FDA would not be required to file an EA if it meets these requirements.

We have determined that this regulation meets the requirements for a categorical exclusion. First, this regulation is clearly not expected to increase cigarette usage. In fact, this regulation is expected to cause a reduction in overall smoking rates and initiation, and we estimate that this rule will reduce the number of smokers by 213,000 in 2013, with smaller additional reductions through 2031. Second, the rule will not affect the way in which cigarettes are used among smokers and it does not change the intended use of cigarettes.

In addition, we have determined that there is no potential for serious harm to the environment resulting from the final rule that would otherwise constitute an extraordinary circumstance (*see* 21 CFR 25.21). Our action to regulate cigarette labeling does not lead to an increase in the level of use of these articles or a change in the intended use of these articles or their substitutes. The primary effect of this regulation will be to reduce smoking initiation and increase cessation efforts. Accordingly, there is no extraordinary circumstance that requires the filing of an EA.

XI. Analysis of Impacts

A. Introduction and Summary

FDA has examined the impacts of the 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). This rule is an economically significant regulatory action under 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. This rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. This rule will result in a 1-year expenditure that meets or exceeds this amount.

Conducting an impact analysis under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act involves assembling any available information that is relevant to the assessment of a regulation's benefits and costs. It is not uncommon in scientific pursuits for there to be a lack of definitive information on some aspects of the question under investigation, and the impact analysis of this final rule is no exception. In light of this situation, we identify and present a range of possible benefits and costs.

The benefits, costs, and distributional effects of the final rule are summarized in table 1a of this document. As the table shows, the midpoint of the estimates for benefits annualized over 20 years is approximately $630.5 million at a 3-percent discount rate and $221.5 million at a 7-percent discount rate. The midpoint for costs annualized over 20 years is approximately $29.1 million at a 3-percent discount and $37 million at a 7-percent discount rate.

The total benefits and costs of the final rule can also be expressed as present values. The midpoint of the estimates for the present value of benefits over 20 years is approximately $9.4 billion at a 3-percent discount rate and $2.3 billion at a 7-percent discount rate. The midpoint of the estimates for the present value of costs over 20 years is approximately $434 million at a 3-percent discount rate and $392 million

at a 7-percent discount rate. With both discount rates, our midpoint estimates indicate that the benefits of the rule greatly exceed the costs. Executive Order 13563, section 1(b), requires that, to the extent permitted by law, agencies proceed with a regulation "only upon a reasoned determination that its benefits justify its costs." The regulation is consistent with this requirement.

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Table 1a.--Summary of Benefits, Costs and Distributional Effects

Economic Data: Costs and Benefits Statement							
Category	Primary Estimate	Low Estimate	High Estimate	Units			Notes
				Year Dollars	Discount Rate	Period Covered	
Benefits							
Annualized Monetized $ millions/year	$221.5	$0	$3,360.7	2009	7%	2012-31	Many of the health benefits included in the totals are realized after 2031 (as far out as 2113), but the smoking preventions that generate these benefits are estimated only for the period from 2012-2031.
	$630.5	$0	$10,916.6	2009	3%	2012-31	
Annualized Quantified					7%		All quantified benefits are also monetized.
					3%		
Qualitative							Reduction in morbidity for dissuaded smokers who do not reach ages 18-24 between 2012 and 2031, reduction in passive smoking, reduction in infant and child health effects due to mothers smoking during pregnancy.
Costs							
Annualized Monetized $ millions/year	$37.0	$34.7	$52.7	2009	7%	2012-31	One-time costs to change cigarette package labels and remove point-of-sale promotions that do not comply with the new restrictions, smaller ongoing costs for equal random display and for government activities.
	$29.1	$27.4	$40.8	2009	3%	2012-31	
Annualized Quantified					7%		
					3%		
Qualitative							Ongoing government costs due to increased traffic to the cessation resource.
Transfers							
Federal Annualized Monetized $ millions/year	$36.6	$0	$237.8	2009	7%	2012-31	Some of the transfers included in the totals occur after 2031 (as far out as 2113), but the smoking preventions that generate these transfers are estimated only for the period from 2012-2031. Numbers reflect the assumption that the Federal cigarette excise tax will rise, on average, at the rate of inflation from 2012-2113. Numbers also include effects on Medicare, Social Security, Medicaid, other government insurance programs and income taxes.
	$76.3	$0	$495.7	2009	3%	2012-31	
From/To	From: Government (more specifically, general taxpayers and recipients of government services)			To: Individuals who would have been smokers in the absence of the rule but will not be smokers in the presence of the rule			
Other	$12.6	$0	$81.7	2009	7%	2012-31	Some of the transfers included in the

Table 1a.--Summary of Benefits, Costs and Distributional Effects

Economic Data: Costs and Benefits Statement							
Category	Primary Estimate	Low Estimate	High Estimate	Units			Notes
				Year Dollars	Discount Rate	Period Covered	
Annualized Monetized $ millions/year	$23.0	$0	$149.4	2009	3%	2012-31	totals occur after 2031 (as far out as 2113), but the smoking preventions that generate these transfers are estimated only for the period from 2012-2031. Numbers reflect the assumption that State cigarette excise tax rise, on average, at the rate of inflation from 2012-2113. Numbers also include effects on Medicaid, other government insurance programs, income taxes, private insurance, pensions and life insurance programs.
From/To	From: Individuals who would have been smokers in the absence of the rule but will not be smokers in the presence of the rule			To: General public (in some cases, via State government)			
Effects							
State, Local or Tribal Government: Each year, State governments will lose approximately $25.1 million in excise tax revenue. There will be additional changes in Medicaid and other government health insurance receipts and outlays.							
Small Business: The proposed rule would affect small entities in several industries, from tobacco farming to the retail industry. In particular, at least 20 of the 24 domestic cigarette manufacturers are small, and the one-time labeling change cost could be a significant proportion of average annual sales receipts of these firms.							
Wages: No Estimated Effect							
Growth: No Estimated Effect							

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Our primary estimate of annualized net benefits equals $601.4 million, with a 3-percent discount rate, or $184.5 million, with a 7-percent discount rate. As shown in table 1b of this document, these net benefits are associated with 16,544 smoking preventions and 5,802 quality-adjusted life-years (QALYs) saved, annualized at a 3-percent discount rate, or 19,687 smoking preventions and 1,749 QALYs saved, annualized at a 7-percent discount rate.

Table 1b.--Annualized Net Benefits, Smoking Preventions and Quality-Adjusted Life-Years Saved

Discount Rate	Net Benefits ($ mil)			Smoking Preventions	Quality-Adjusted Life-Years Saved
	Primary Estimate	Low Estimate	High Estimate	Primary Estimate	Primary Estimate
7%	184.5	-52.7	3,326.0	19,687.1	1,749.4
3%	601.4	-40.8	10,889.2	16,544.3	5,802.5

FDA's estimate of the benefits of the rule is determined by the predicted reduction in the number of U.S. smokers and the consequent reduction in the number of people who will ultimately become ill or die from diseases caused by smoking. In the first step of our analysis, we conclude that graphic warnings on cigarette packages will reduce smoking rates (both by encouraging smokers to quit and by deterring nonsmokers from starting). This conclusion is based on an analysis of the experience of Canada, which introduced graphic warnings on cigarette packages in December 2000. By comparing smoking rates in the United States with those in Canada and accounting for other relevant differences between the two countries, we are able to isolate the effect of graphic warnings on smoking rates from the effects of other interventions to reduce smoking in Canada and the United States. This comparison yields an estimate of how the graphic warnings required by this rule will reduce smoking rates in the United States. FDA estimates that this rule will reduce the number of smokers by 213,000 in 2013, with smaller additional reductions through 2031.

This estimated drop in the smoking rate in turn allows us to estimate benefits that will accrue to dissuaded smokers and to other members of society. Some individuals whose smoking status is not affected by the required graphic warning labels will receive benefits from the rule-induced reductions in smoking-related fires and certain financial outlays, such as life insurance premiums that are not actuarially fair,[10] that implicitly subsidize smoking. Individuals who are dissuaded from smoking by the rule receive benefits equal to the value of cessation or avoided initiation. We use two methods of estimating this value, one that extrapolates from the price of actual cessation programs and one that measures the excess value of health improvements, over and above what smokers give up by not engaging in the activity of smoking. Our estimates of health improvements include the monetized value of life extensions, the monetized benefits from improved

[10] The term "actuarially fair" refers to insurance premiums that are exactly equal to expected losses.

health status (avoided nonfatal health consequences or morbidity from smoking), and reductions in medical costs. We do not have direct estimates for the value smokers attach to the activity of smoking, which adds some uncertainty to the second benefits estimation method. We therefore present several benefits estimates for which there is some justification in the literature or in comments on the proposed rule. For each discount rate and value of a statistical life-year (VSLY), our primary benefits result is the midpoint between the lower and upper bound values generated by the multiple estimation methods. Table 2 of this document shows the benefits broken down into the value of gained life-years, improved health status, medical cost reductions, other financial effects, and reduced fire-related losses. Most of the public health benefits from the rule will be realized in the future, perhaps several decades after the rule takes effect.

The estimated totals may understate the full public health benefits of the rule because they fail to quantify reductions in external effects attributable to passive smoking and the reduction in infant and child morbidity and mortality caused by mothers smoking during pregnancy. These benefits are likely to be significant, but FDA has been unable to obtain reliable data with which to quantify them with greater precision than an order-of-magnitude approximation which will be discussed in the ''Benefits'' section of this Analysis of Impacts. In particular, we were not able to project future levels of exposure to secondhand smoke (passive smoking) from historical trends. We were also unable to quantify reductions in the cost of excess cleaning and maintenance costs caused by smoking.

Table 2.--Benefits of Regulation

Impacts of the Rule	Annualized Benefits ($ mil)					
	3 percent			7 percent		
	Low	Medium	High	Low	Medium	High
Smokers' Life-Years Saved	237.6	465.1	692.7	66.1	132.4	195.9
Health Status Improvements	49.9	97.8	145.6	22.8	45.7	67.6
Medical Expenditure Reduction	28.0	27.7	27.6	22.8	22.8	22.6
Other Financial Effects	27.4	27.5	27.6	15.4	15.4	15.5
Fire Loss Averted	7.1	12.4	17.6	3.2	5.2	7.2
TOTAL	349.9	630.5	911.1	130.3	221.5	308.8

Note: Table entries are annualized over 20 years, but many of the benefits represented will not be realized until well beyond the 20th year of the rule's implementation. (Details of timing appear in Technical Appendix X3.) The ranges in the table are generated by three values of a statistical life-year: $106,308 (low), $212,615 (medium), and $318,923 (high).

The total estimated costs of implementing cigarette graphic warning labels include $319.5 million to $518.4 million in one-time costs and $6.6 to $7.1 million in annual recurring costs. Annualized over 20 years, the total costs range from $27.4 million to $40.8 million with a 3-percent discount rate and from $34.7 million to $52.7 million with a 7-percent discount rate, as shown in table 3 of this document. These totals include the costs to manufacturers of changing cigarette labels, the administrative and recordkeeping costs to manufacturers of ensuring equal and random display of the nine different warning labels over time, the costs to large manufacturers of market-testing new cigarette package labels, and the costs to manufacturers and retailers of removing point-of-sale advertising that does not comply with the rule. There are also costs to the Government of administering and enforcing the rule. FDA could not quantify every regulatory cost. Some commercial sectors will experience costs for short-term dislocations of current business activities, but the costs will be mitigated for those businesses that anticipate the industry's adjustments to the final rule.

In addition to the costs described previously, the rule will lead to private costs in the form of reduced revenues for many firms in the affected sectors. These sector-specific revenue reductions are for the most part distributional effects and cannot be counted as social costs.

Table 3.--Costs of Regulation

Requirements of the Rule	Annualized Costs ($ million)					
	3 percent			7 percent		
	Low	Med	High	Low	Med	High
Private Sector						
Label Change	17.8	19.3	30.3	24.0	26.0	41.0
Market Testing	0.1	0.1	0.5	0.1	0.2	0.7
Point-of-Sale Advertising	3.0	3.0	3.0	4.0	4.0	4.0
Continuing Admin and Recordkeeping	0.4	0.6	0.8	0.3	0.6	0.8
Subtotal	21.2	23.0	34.7	28.5	30.8	46.5
Government						
FDA	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)						
Subtotal	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	27.4	29.1	40.8	34.7	37.0	52.7

As tobacco industry revenues decline, State and Federal tobacco tax revenues will also fall. If excise tax rates on tobacco products remain at current levels, annual State tax revenues will fall by approximately $25.1 million and annual Federal tax revenues by $19.3 million.

In the following section, FDA responds to comments on the economic analysis of the proposed rule. The full economic analysis of the final rule begins in section XI.C of this document.

B. Comments on the Preliminary Regulatory Impact Analysis

1. General

In the Preliminary Regulatory Impact Analysis (PRIA), FDA estimated various benefits, costs and transfers brought about by the graphic warning label rule. We received comments on the PRIA from approximately seven tobacco manufacturers or industry groups, one advertising industry group, four nonprofit organizations, a group of researchers and an individual researcher affiliated with a medical school, two economists submitting on behalf of the tobacco industry, one additional economist, and several private citizens. Two comments related to the scope of the effects that should have been estimated in the PRIA and to a parameter choice that affected several portions of the analysis.

(Comment 212) One comment stated that FDA's use of a 7-percent discount rate is not appropriate.

(Response) The use of both 3-percent and 7-percent discount rates is standard practice in regulatory impact analysis and is required by OMB Circular A–4 (Ref. 103).

(Comment 213) One comment stated that FDA should measure the scope of the following potentially rule-induced phenomena: Increases in the purchase of illicit cigarettes (counterfeits, contraband, cheap whites, *etc.*), increases in the presence of nondomestic products (duty-free, *etc.*), and decreases in the presence of legal domestic products.

(Response) FDA has performed a quantitative analysis of the regulation's effect on domestic cigarette consumption (sections XI.D.1 and Technical Appendix X6) and a qualitative analysis of the international effects of the regulation (section XI.H of this document). FDA agrees that it would be useful to include the effect of the rule on illicit cigarette trading in the regulatory impact analysis. However, due to data limitations, FDA has been unable to quantify this effect.

2. Need for the Rule

In the preliminary impact analysis of the graphic warning label rule, FDA cited our statutory mandate as the primary need for the regulation. We received a comment stating that we had failed to discuss the economic rationale for the rule.

(Comment 214) One comment stated that FDA, in the preliminary Analysis of Impacts, failed to identify the market failure that the regulation is addressing. The comment went on to state that warning labels are a means of disseminating information, and if consumers are already fully informed about a particular product, there can be no increase in consumer welfare due to the addition or revision of a warning label.

(Response) An absence of adequate information is a well-established market failure, one which provides a rationale for disclosure requirements. There is evidence that smokers may not be fully informed of the risks associated with cigarette smoking and that large graphic warning labels can be more effective at providing information than small, text-only warnings. There is also evidence that those who have an accurate understanding of the *statistical* risks may underestimate their *personal* risks; and even where consumers have an accurate understanding, the risk might not be considered at the time of purchase (Ref. 183).

Evidence on some of these points is provided by O'Hegarty *et al.* (Ref. 111), who find that young American consumers are aware of some health consequences of smoking, such as the increased probability of lung cancer, but not of others, such as the increased probability of stroke. Other evidence on this question comes from Khwaja *et al.* (Ref. 112), who find that smokers aged 50 to 65, unlike their nonsmoking counterparts, underestimate their personal probability of dying within the next 10 years. Borland and Hill (Ref. 63, Borland 1997) find that Australia's requirement of larger warning labels increased tobacco consumers' knowledge that smoking causes cancer, heart and circulatory illnesses, and pregnancy-related problems. O'Hegarty *et al.* (Ref. 111) report that American focus group members anticipate that Canadian-style large, graphic warning labels would be more effective at communicating health information than the labels currently required in the United States. Evidence from the International Tobacco Four-Country Survey (Ref. 26, Hammond 2006) supports this conclusion, with Canadian smokers more likely than smokers from the United States, United Kingdom, or Australia—countries that required only text warnings at the time of the survey—to know that smoking causes heart disease, stroke, and impotence and that cigarettes contain such chemicals as carbon monoxide and cyanide.

The U.S. Census indicates that nearly 11 million respondents in the year 2000 did not speak English well or very well (Ref. 102); the non-English-speaking population has likely increased in the intervening years. Moreover, the Department of Education reports that, in 2003, 30 million American adults, aged 16 and over, possessed ''below basic'' prose literacy skills (Ref. 113). Images of smoking's consequences and translation of warnings into Spanish and other languages can provide health information to consumers who lack English literacy.

FDA also notes that the economics and psychology literatures suggest several rationales, other than incomplete or imperfect information, for policy intervention in the realm of smoking. The growing literature on myopia, self-control, and time-inconsistency examines situations in which consumers may overvalue (relatively modest) short-term benefits and undervalue (relatively large) mid-term or long-term harms. The theoretical and empirical evidence suggests the possibility that through their decisions at early stages, smokers may impose significant costs on their future selves, producing net losses in terms of welfare; if so, these costs might legitimately be taken into account for purposes of policy. Helping to inaugurate the modern literature, Thomas Schelling suggests in a series of papers that smoking and similar behaviors characterized by attempts to quit and relapses can be interpreted as a contest between two selves: One self trying to stop smoking for health reasons and the other self wanting to continue to smoke. These alternating preferences violate the assumption of stable preferences and can provide a rationale for policy interventions (Refs. 106, 107, and 108).

Discussing another potential rationale for policy intervention, Gruber and Köszegi (2001) (Ref. 104) state: ''While the rational addiction model implies that the optimal tax on addictive bads should depend only on the externalities that their use imposes on society, the time inconsistent alternative suggests a much higher tax that depends also on the 'internalities' that use imposes on consumers.'' With the graphic warning label rule, FDA is undertaking a policy option that, like a tax, can induce lower cigarette consumption, and we reach a conclusion similar to that of Gruber and

Köszegi; we find that individuals who are dissuaded from smoking are made better off (*i.e.,* they receive a net benefit) as a result of government policy intervention. (We note that Gruber and Mullainathan (Ref. 182), using subjective well-being data, find that one regulatory tool—excise taxation—has a positive effect on the happiness of those with a propensity to smoke, a result consistent with the results we present in this analysis.)

Bernheim and Rangel (Ref. 105) find that the benefits of smoking (realized by smokers themselves) are less than the realized health costs, but chemical reactions in the brain cause the consumer to mistakenly forecast more benefits when making consumption choices than he or she actually realizes from consuming the addictive product. These authors suggest that this overestimation occurs through a flawed hedonic forecasting mechanism in which particular environmental cues lead a smoker to move into a ''hot'' state in which he or she overestimates the pleasure from smoking. This analysis suggests that graphic warning labels may be able to serve as counter-cues that prevent movement into the hot state and allow the addict to continue to exercise self-control.

Laux (Ref. 109) identifies other reasons that smokers may not fully internalize the costs of their addictive behavior, including teen addiction as an intrapersonal (two selves) externality, partially myopic adult behavior, and peer effects.

According to the model developed by Gul and Pesendorfer (Ref. 110), if graphic warning labels reduce the temptation associated with the addictive product, they will reduce smoking and increase social welfare.

3. Benefits

In the preliminary impact analysis, FDA estimated a variety of welfare-enhancing effects of the graphic warning label rule; these included reductions in smoking-related mortality, morbidity, medical expenditures, and fire damage. We received many comments on the methods, assumptions, choice of sources, and results that were reported in the benefits analysis.

(Comment 215) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too low, in that it ignored the rule's effect on initiation, in favor of a cessation-only analysis.

(Response) For both the proposed rule and the final rule, FDA has analyzed the national adult smoking rate (*i.e.,* the nation's smoking population divided by the nation's total population). The smoking rate at any particular moment is a function of all past initiation, cessation, birth, death, and migration of smokers and nonsmokers across national borders. Therefore, our approach includes the effect of the rule on initiation.

(Comment 216) One comment stated that FDA's preliminary estimate, that only 82,000 individuals would be dissuaded from smoking between 2014 and 2031, was too low.

(Response) FDA's estimate that the rule-induced reduction in U.S. smoking population will occur mostly during the first year after implementation of graphic warning labels is a product of the simplicity of our empirical model. We agree that a time trend of the effect of the rule is to be preferred over a single average effect. However, our attempts to estimate linear or quadratic time trends have produced highly implausible results, especially for projections furthest into the future. We are then left with a best estimate of how the rule would decrease the U.S. smoking rate in which the number of dissuaded smokers is smaller for any year from 2014 to 2031 than for 2013. This estimated change is not a decrease from year to year (*e.g.,* 2013 to 2014), but a net decrease for a given year in the presence of the rule compared with the same year in the absence of the rule.

(Comment 217) Two comments stated that FDA's preliminary estimate of smoking rate reduction was too low, in that it ignored the fact that someone who is dissuaded from smoking in 1 year will likely remain a nonsmoker in future years.

(Response) FDA notes that the likelihood that an individual dissuaded from smoking in a particular year will likely continue to be a nonsmoker in subsequent years was accounted for by our preliminary estimate, which had the U.S. smoking rate continuing to be lower than it otherwise would have been in years 2014 through 2031, not just in 2013. The same characterization holds for the estimate in FDA's Final Regulatory Impact Analysis.

(Comment 218) One comment stated that ''Canada has used graphic warnings for years, and in the last decade their smokers dropped from 23% to 22% of the population.''

(Response) Canada's smoking rate has decreased by around seven percentage points, not one, since the implementation of graphic warning labels in late 2000. Even if the one percentage point statistic was correct, a one percentage point decrease in the smoking rate would not be a small change when applied to the large population of the United States; in fact, it would imply that there would be more than 3 million dissuaded American smokers.

(Comment 219) One comment stated that the required label change would have very little impact on smoking rates because minors, who form the bulk of new smokers, obtain their cigarettes from parents rather than from retail establishments.

(Response) Due to lack of data, FDA's estimates of the amount of smoking cessation or avoided initiation brought about by the rule include only adults aged 18 and above, or young persons who reach age 18 by the year 2031. The number of minors dissuaded from smoking by the rule may be substantial. Whether they obtain cigarettes from friends, through theft, or by purchasing them from retail establishments operating in violation of youth access laws, young people will be exposed to new graphic warning labels because the labels are printed directly on cigarette packages.

(Comment 220) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too high, in that it did not address potential competitive responses of the cigarette companies to the proposed rule. The comment went on to state that, under the proposed rule, graphic warning labels would take up a substantial portion of the area in packaging and advertising where firms establish brand recognition, thus reducing consumers' ability to distinguish premium from discount brands. This would cause premiums for branded cigarettes to decrease and price competition to intensify, which in turn would likely lead to an increase in cigarette usage.

(Response) FDA believes that, even if well-known brands only have half a package with which to advertise themselves, they still have name recognition. We expect that consumers will continue to be able to find their preferred brands; as a result, any change in prices due to competitive pressures is likely to be small.

The cigarette producers' strategic responses suggested by the comment should have occurred in Canada when that country implemented graphic warning labels. Because FDA's estimate of the effect of graphic warning labels is based on the Canadian experience, we implicitly account for any decrease in the price of cigarettes caused by competition between premium and discount brands. Our point estimate indicates that the net effect of graphic warning labels is a decrease in the national smoking rate in spite of this possible offsetting effect.

(Comment 221) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too high, in that it failed to recognize or control for other regulatory changes (such as smoking bans) affecting cigarette consumption at the State, provincial, or municipal levels.

(Response) FDA acknowledges that our model does not explicitly allow for many potential confounding factors, but we note that our estimates of the effect of graphic warning labels could as easily be underestimates as overestimates. More specifically, our model will produce an overestimate if: Smoking-reducing phenomena (other than graphic warning labels) were growing in prevalence or effectiveness at a faster rate in Canada after 2000 than before 2001, smoking-reducing phenomena (other than graphic warning labels) were more prevalent or effective in Canada than in the United States after 2000, or smoking-reducing phenomena (other than graphic warning labels) were less prevalent or effective in Canada than in the United States before 2001. In the opposite cases, our model will produce an underestimate. In the absence of extensive high-quality data, we assume that trends in smoking-reducing phenomena (other than graphic warning labels) were about the same before and after the year 2000 and about the same in Canada and the United States.

(Comment 222) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too high, in that it did not account for potential differences in responder bias between United States and Canadian surveys created by different levels of stigma associated with smoking in the two countries.

(Response) FDA generates its estimate not only by comparing Canada with the United States but also by comparing each country with itself. Specifically, we find the difference between each country's actual 1994 through 2009 smoking rates with rates predicted by a pre-2000 trend (which accounts for changes in cigarette taxes), and then calculate how the average difference for 2001 through 2009 compares with the average difference for 1994 through 2000. The trend at least partially controls for any steady change over time in responder bias within a given survey, and the within-country comparison of pre-2001 and post-2000 rates controls for any difference in responder bias between the two countries.

(Comment 223) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too high, in that it did not account for differences in cigarette prices over time in the United States and Canada.

(Response) For the analysis of the final rule, FDA has incorporated changes in Canadian and United States tax rates into its estimates.

This comment suggests elsewhere that graphic warning labels will cause prices to decrease. FDA agrees that this is a possibility. Thus, for the non-tax portion of cigarette prices, we are faced with what economists call an endogeneity problem; it is difficult to determine, in an empirical analysis in which price is used directly as a control variable, the direction and magnitude of causality. However, if the changes in the non-tax portion of prices in the United States and Canada follow the same pattern post-2000 as they did pre-2001, and if the relationship between smoking status and cigarette prices was also relatively constant between the two time periods, then our smoking rate trends successfully control for the effect of non-tax price changes on smoking rates.

(Comment 224) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too high, in that it did not account for the fact that Canada's Tobacco Act's prohibitions on advertising and promotion came into full effect after the introduction of the graphic cigarette labels. The comment went on to state that other local regulations (such as restrictions on the retail display of tobacco products and advertisements) that came into effect in Canada after the year 2000 also may have had an effect on smoking rates in Canada, and thereby would have inflated FDA's estimate of the expected rule-induced reduction in smoking rates.

(Response) From 2001 to 2008, at least 41 states, plus the District of Columbia, enacted or substantially updated legislation regarding tobacco advertising and promotion, youth access or sampling and distribution (Ref. 114). FDA concludes, therefore, that the U.S. experience provides a reasonably good control for the effect of local and regional policy changes on national smoking rates.

(Comment 225) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too high, in that it failed to account for the fact that, in April 2001, the Government of Canada launched a Federal public education, outreach, and mass media campaign that had a goal of reducing tobacco-related death and disease among Canadians.

(Response) The U.S. experience provides a reasonably good control for the effect of media campaigns on smoking rates because antismoking initiatives have been active in the United States in the past decade. For example, the ''Truth'' Campaign, a nationwide advertising effort aimed at discouraging youth smoking, launched in the United States in 2000 and continued into the 2000s.

(Comment 226) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too high, in that it failed to account for the fact that individuals over age 65 are less likely to be smokers than younger individuals and Canada's population is aging more rapidly than that of the United States. Specifically, during the period 2001 through 2009, Canada's over-65 population grew by 21 percent while the U.S. over-65 population grew by only 12 percent. Canada's over-65 population represented 13.9 percent of its total population in 2009, up from 12.9 percent in 2001. This compares to the U.S. over-65 population which increased to 12.9 percent in 2009, up from 12.4 percent in 2001.

(Response) FDA notes that the comment's finding (that individuals over age 65 have a lower probability of being smokers than individuals aged 65 and below) does not necessarily imply that aging causes individuals to cease smoking. Smoking rates are much lower in the over-65 age category than in the 65-and-under category because smokers are less likely than nonsmokers to survive to and live past the age of 65.

Possible reasons for the aging of a nation's population include: A decrease in the birth rate, net emigration of relatively young people, net immigration of relatively old people, a decrease in the death rate of relatively old people, or an increase in the death rate of relatively young people. If the changes in these population phenomena in the United States and Canada follow the same pattern post-2000 as they did pre-2001, and if the relationship between smoking status and the population phenomena was also relatively constant between the two time periods, then our smoking rate trends successfully control for the effect of population changes on smoking rates. (Of course, there is a correlation between smoking rates and death rates, but it operates with sufficient lag so as not to confound our results to a meaningful degree.)

(Comment 227) Several comments suggested that the lack of statistical significance of FDA's estimate of the effect of graphic warning labels on Canada's smoking rate implies that there is no sound basis for concluding that the proposed (and now final) rule's benefits exceed costs and that this creates a

violation of Executive Order 12866, which requires government agencies to show the quantitative benefits exceed the quantitative cost from a regulation. One comment further noted that FDA did not, in the preliminary analysis, report whether its secondary methodology (in the Uncertainty Analysis) produced an estimate that was statistically significant.

(Response) Executive Order 12866 states that: ''Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.'' The point estimates indicate that the benefits of the rule justify the costs. Although our analysis concludes, on this basis, that graphic warning labels will be effective at reducing smoking, we recognize there is large uncertainty about the size of the effect. The lack of statistical significance in FDA's smoking rate estimate reflects this uncertainty, as well as the noisiness of data derived from surveys and the small number of observations.

The use of a point estimate (which indicates that graphic warning labels have decreased the smoking rate in Canada) is appropriate for the main portion of our analysis as long as we state clearly the lack of statistical significance. Moreover, in the final analysis, we report the results of Monte Carlo simulations to better show the uncertainty. In doing so, we follow the advice of Vining and Weimer (Ref. 115): ''In view of the large number of uncertain effects and shadow prices involved in applying BCA [benefit-cost analysis] to social policies, analysts must take special care in dealing with uncertainty. Rather than setting estimates of effects equal to zero when their estimates are statistically insignificant, a more appropriate approach is to take account of the uncertainty of these effects in Monte Carlo simulations.''

In addition to reporting Monte Carlo results, FDA has added additional discussion which will allow the interested reader to examine our empirical approaches in greater detail.

(Comment 228) One comment stated that FDA has no explicit measures linking each graphic warning label with expected reductions in the risks of cigarette smoking. An example of such linking would include answering the following questions: What percentage of smoking mothers blow smoke into their children's faces, what is the probability that such behavior leads to cancer, and how much cancer reduction will be effected by the graphic warning label that depicts a baby being exposed to secondhand smoke?

(Response) The research study commissioned by FDA and included in the docket analyzes the reactions of consumers to each image. We cannot yet know the effectiveness of each image on improving health outcomes (such as avoidance of cancer) because the images have not yet appeared on cigarette packages or advertisements. Our best estimate of the images' collective effect comes from Canada's experience with a collection of graphic warning labels.

(Comment 229) One comment stated that FDA should use worldwide data if its model of smoking reduction cannot achieve statistical significance using only Canadian data.

(Response) FDA disagrees because, culturally and geographically, Canada provides a closer comparison for the United States than any other country. Moreover, in most countries, graphic warning labels have been implemented for only a few years, so any international additions to our data set would likely contribute only a small number of data points while simultaneously necessitating the addition of extra variables (for example, geographic and time fixed effects) into the model, thus producing only a small overall increase in degrees of freedom and introducing potential errors due to more omitted variables.

(Comment 230) One comment stated that FDA should use data from New York City's experience with a graphic image media campaign, which reduced smoking prevalence in that State by 1.4 percentage points between 2005 and 2006.

(Response) FDA prefers the Canada-United States empirical model over a potential New York model both because Canada's graphic warning policy is much more similar to the present rule than is New York's television-based campaign and because Canada's policy has been in place for a longer period of time than New York's, thus providing more data points. Furthermore, we note that the New York experience would likely yield a much lower (than 1.4 percentage points) estimate of the effect of graphic images if only the excess smoking rate changes, beyond New York's own trend and the changes experienced simultaneously in comparable cities or States, were included.

(Comment 231) Several comments stated that Sloan and coauthors' estimates of the number of life-years lost by smokers are too low and recommended that FDA use other, higher estimates that appear in the scholarly literature.

(Response) The comments making this point have confused the life-years lost for a lifetime smoker (compared with a nonsmoker or quitter) with the measure that FDA needs for its analysis: the adjusted life expectancy changes that make up the incremental effects of reduced smoking rates induced by the final rule.

Regarding life-years lost for a lifetime smoker (compared with a nonsmoker or quitter), Sloan and coauthors' estimates (Ref. 116) do not differ much from those reported in other studies. Specifically, Sloan *et al.* use results from the Taylor *et al.* (Ref. 117) study, which reports that men who quit smoking at age 35 gain 8.5 years of life expectancy and male never-smokers gain 10.5 years. In comparison, Doll *et al.* (Ref. 118) find that if an individual avoids smoking entirely or quits at age 30, he increases his life expectancy by 10 years. Strandberg *et al.* (Ref. 119) find that smoking shortens life expectancy for males by 7 to 10 years.

Sloan *et al.* adjust the Taylor *et al.* results to account for the probability that an individual who smokes at a given age will quit sometime later in his or her life and for confounding factors, such as differences in demographic characteristics and behaviors between average smokers and nonsmokers. Unlike Sloan *et al.,* the studies cited in comments estimate the longevity gains to an individual from not smoking or from quitting at a given age but do not incorporate the *probabilities* of quitting at each age or isolate the effect of cigarette consumption from other risk factors that tend to be correlated with smoking. These studies are therefore inappropriate for a regulatory impact analysis estimating the incremental effects of warning labels on lifetime mortality consequences related to smoking at a particular age.

(Comment 232) Two comments expressed concern that Sloan and his coauthors' analysis is outdated. One of the comments went on to state that Sloan *et al.'s* literature review contains some studies that have been funded by the tobacco industry and their ''defense of rational addiction'' may be undermining FDA's effort to ''ensure that its economic analysis is based on empirical evidence, not theoretical predictions from the rational addiction model.''

(Response) The Sloan *et al.* results that FDA uses are empirical, not theoretical. In producing these empirical results, Sloan and coauthors use data from the 1990s; while this is somewhat out-of-date, no analysis as

detailed as that of Sloan *et al.* has been released more recently. The comment critiques some of the literature reviewed by Sloan and coauthors but not the methods Sloan *et al.* use to produce their life tables and other results. FDA has thus continued to use these results in its Final Regulatory Impact Analysis.

(Comment 233) One comment stated that the FDA provided in its preliminary Analysis of Impacts virtually no details on its calculation of the benefit of expected life-years saved.

(Response) FDA has added a more detailed explanation to the final Analysis of Impacts.

(Comment 234) One comment stated that, in its estimate of rule-induced emphysema reductions, FDA did not provide any documentation supporting its calculations.

(Response) FDA has replaced its analysis of rule-induced emphysema reductions with an analysis of general health effects. Simultaneous with this change has been an expansion of our explanation of methodology.

(Comment 235) Several comments stated that morbidity effects other than emphysema were inappropriately excluded from FDA's preliminary analysis.

(Response) FDA has expanded its morbidity estimates for the final Analysis of Impacts. Instead of analyzing individual diseases, we have calculated rule-induced changes in general health status (categorized as poor, fair, good, very good, or excellent).

(Comment 236) Several comments stated that benefits due to reductions in secondhand smoke exposure and mothers smoking during pregnancy were inappropriately excluded from FDA's preliminary analysis.

(Response) FDA did not exclude discussion of these effects from the preliminary Analysis of Impacts, but we were not able to quantify them due to the difficulty of projecting future secondhand smoke exposure levels from historical trends. Similarly, we were not able to project future reductions in maternal smoking during pregnancy. In the Final Regulatory Impact Analysis, FDA has again been unable to quantify these benefits.

(Comment 237) One comment stated that FDA's analysis includes only health benefits that accrue in the distant future, not immediate benefits of cessation or avoided initiation.

(Response) FDA's preliminary and final estimates of morbidity and mortality effects include discounted totals of all future effects, both short-term and long-term. For example, we obtained our life expectancy estimates from Sloan *et al.*'s life tables. Calculated for 24-year-olds, these tables include survival probability differences for smokers and nonsmokers as early as the 25th birthday.

(Comment 238) One comment stated that FDA's assumptions regarding the distribution of benefits over dissuaded smokers' lifetimes were incorrect.

(Response) In many cases, FDA's sources reported smoking-related effects only as present values calculated with a single discount rate and for a particular age group. In order to expand our results to other age groups or discount rates, it was necessary that we make assumptions about the timing of benefits. The absence of data prevents FDA from confirming the degree of inaccuracy of our assumptions. For the final analysis, we have expanded our discussion of the likely direction of estimation error that may be caused by our assumptions and, in one case, have accounted for uncertainty related to assumption-making in our Monte Carlo analysis.

(Comment 239) One comment stated that Sloan *et al.*'s estimates of smoking-attributable medical cost ($3,757 per female and $2,617 per male) are too low. The comment went on to recommend the use of Thomas Hodgson's estimate (Ref. 120) that this cost, in 2009 dollars and discounted at a 3 percent rate, is $18,967.

(Response) FDA believes that Sloan *et al.*'s estimates are to be preferred over Hodgson's because Hodgson does not adjust for confounding effects (by analyzing ''nonsmoking smokers,'' a theoretical comparison group Sloan *et al.* used to account for the effects of other risky behaviors) and Sloan *et al.*'s data sets are more recent (from the 1990s, rather than 1978 through 1988).

The comment calculates the present-dollar value of Hodgson's medical cost estimates using the medical component of the consumer price index (CPI). For the Final Regulatory Impact Analysis, FDA will do the same because medical costs have risen at a very different rate than overall price levels and thus the measure of inflation we used in the PRIA—the gross domestic product (GDP) deflator—is not the best available option for updating medical costs.

(Comment 240) One comment stated that FDA's medical cost results were not adjusted for inflation in the preliminary Analysis of Impacts.

(Response) FDA's medical cost estimates were adjusted for inflation in the analysis of the proposed rule; however, our language on this issue was unclear and has been revised for the analysis of the final rule.

(Comment 241) One comment stated that, in the preliminary analysis, FDA provided only a very high-level and cursory description of how it arrived at its estimate of reduced fire costs.

(Response) For the final analysis, FDA has expanded the discussion of how fire loss reductions were calculated.

(Comment 242) One comment stated that FDA's assumption that the introduction of self-extinguishing cigarettes would reduce the incidence of smoking-related fires, with or without the proposed rule, by 50 percent was arbitrary.

(Response) FDA agrees that the 50 percent assumption lacked empirical support. For the final analysis, we use a data-driven estimate of the effectiveness of self-extinguishing cigarettes at preventing accidental fires.

(Comment 243) Two comments stated that FDA's preliminary benefits analysis inappropriately excluded effects of the rule on employee productivity.

(Response) FDA estimates morbidity and mortality effects using a willingness-to-pay approach, estimated using the QALY metric as the base. Willingness-to-pay to avoid morbidity, as we use it in this analysis, includes the subjective value of avoiding an illness that affects mobility, self-care, usual activities (including work), pain or discomfort, and anxiety or depression. These elements encompass the value of market and nonmarket productivity, and much else. Therefore, in general, the value to smoking employees of productivity effects is implicitly included in both morbidity and mortality benefits; adding productivity effects separately would almost certainly lead to double counting of some of the benefits that accrue to dissuaded smokers. Economic theory predicts that, for employers, rule-induced productivity effects generate no long-term net benefit or cost because greater firm output will be offset by the greater wages commanded by the more productive employees.

(Comment 244) One comment stated that ''FDA's analysis could benefit from a more fulsome explanation of the concept of QALY.''

(Response) FDA has edited the final analysis accordingly.

(Comment 245) FDA received several comments in regard to its downward adjustment of benefits estimates to account for consumer surplus loss. One comment stated that such an adjustment should not be performed at all because doing so requires an inaccurate assumption that smokers enjoy smoking. Three comments suggested that, if an adjustment is performed, it should not be 50 percent of gross health benefits, as suggested in FDA's cited reference, because that analysis assumes perfect

rationality on the part of smokers. Another comment objected to the model in the cited reference because it is very simplified and stylized, with a linear demand curve for smoking. One of the comments suggested FDA should instead consider modern economic analyses of addiction that account for time inconsistencies in preferences, including the work of Fritz Laux (Ref. 109) or Jonathan Gruber and Botond Köszegi (Ref. 104). Another of the comments suggested past regulatory changes and their effect on smoking be used to measure demand and the lost surplus associated with those changes to get a more empirically relevant measure of the effect of the proposed rule.

(Response) The concept of consumer surplus is a basic tool of welfare economics. If consumers respond to price, information, or other market changes, there will be a change in consumer surplus. Although some economists describe consumer surplus as a measure of the pleasure, satisfaction, or usefulness that a product provides to consumers, others simply say that whatever generates a demand for the product generates consumer surplus. Moreover, how we qualitatively describe consumer surplus does not affect how it is measured—the measurement is independent of the description. In an analysis of benefits based on willingness-to-pay, we cannot reject this tool and still fulfill our obligation to conduct a full and an objective economic analysis under Executive Orders 12866 and 13563.

Although it does not affect our use of consumer surplus, we note that virtually all studies of the economics of smoking and addiction assume that smoking is pleasurable to smokers. In their 2001 paper in *The Quarterly Journal of Economics,* Gruber and Köszegi state that ''smoking is a short-term *pleasure''* (emphasis added) (Ref. 104). Economists Warner and Mendez state: ''Many members of the tobacco control community dismiss the notion that smoking can be pleasurable. But those people were never smokers or, if they were, have selective memory. For some smokers, the relief of withdrawal symptoms might suffice as a 'pleasure.' But smokers derive much more from their cigarettes, including everything from 'mouth feel' to the nicotine drug rush, from relaxation to self-image (think Marlboro Man), and from enhanced ability to concentrate to companionship'' (Ref. 121).

FDA's approach to the economics of smoking treats it as an addiction and draws on many economic theories of addiction, including the studies cited in the comments, as already detailed in our response to comments on market failure.

FDA agrees that the model we used in the PRIA to explain changes in consumer surplus is not detailed enough to fully explain the assumptions about consumer behavior underlying our estimates. In the revised analysis, we have made some important changes in the presentation and the model used to adjust our estimates and account for uncertainty. The key assumption made explicit in the new model is that, on average, smokers are informed of, and able to internalize, some but not all health and life expectancy effects of their smoking. Full graphical and algebraic analyses have been added to the final analysis, as has a discussion of the implications of Gruber and Köszegi's work in the context of the new model. Moreover, we have supplemented our benefits analysis with another approach, in which we replace the steps of summing all health effects and then subtracting lost consumer surplus with a direct estimation of the value to smokers and potential smokers of cessation and avoided initiation, as shown by their willingness-to-pay for cessation programs.

(Comment 246) One comment stated that FDA's preliminary benefits analysis inappropriately excluded the effects of the rule on employer and government cleaning and maintenance costs.

(Response) Reductions in the cost of cleaning and maintenance were not included in the analysis because we did not find reliable data.

(Comment 247) One comment stated that FDA should conduct its uncertainty analysis by performing a Monte Carlo simulation.

(Response) FDA agrees and has conducted a Monte Carlo simulation for the Final Regulatory Impact Analysis.

(Comment 248) Two comments stated that FDA's preliminary analysis inappropriately excluded the effects of the rule on government-funded health care and Social Security expenditures.

(Response) In our analysis of the proposed rule, FDA did not exclude government health care costs. In section VIII.C.6 of the PRIA, FDA reported estimates of reductions in smoking-related medical expenditures, paid for both by smokers themselves and by nonsmokers via insurance premiums or, notably, taxes used to fund government health care. For the Distributional Effects portion of the Final Regulatory Impact Analysis, we have expanded the discussion of this effect of the rule to include greater detail.

We have also added a discussion of Social Security payments to the Distributional Effects section of the final analysis. We note, however, that the cost to taxpayers of Social Security are exactly offset by payments to Social Security recipients or users of any other government programs and services funded with Social Security contributions, so this effect does not generate a substantial net social cost or benefit, with the exception of a probably small deadweight loss.

(Comment 249) One comment stated that the FDA's preliminary analysis did not, as required by the Office of Management and Budget, provide a year-by-year schedule of undiscounted cash flows that displays the timing of estimated rule-induced benefits.

(Response) FDA has added stream-of-benefits and -costs tables as appendices to the final analysis.

4. Costs

In the analysis of the proposed rule, FDA focused on three main costs to industry: The cost of changing cigarette package labels, the cost of conducting market testing for redesigned packages, and the cost of removing noncompliant point-of-sale advertising. FDA received several comments about costs, which are summarized and responded to in the following paragraphs.

(Comment 250) One comment took issue with FDA's characterization of the up-front costs associated with a major label change as ''large'' by pointing out: ''In the context of tobacco marketing, with the companies spending $12.5 billion on marketing and promotion in 2006, the amounts of money being described are not 'large.'''

(Response) FDA has removed the term ''large.''

(Comment 251) One comment asserted that the cost section was systematically biased, and that all costs were upper bound estimates as opposed to ''best'' point estimates.

(Response) FDA did not rely on upper bound estimates of any costs. The label change costs (the largest single cost component FDA estimated) and the market testing costs have low, medium, and high estimates. For the other cost components, we use our best estimates.

(Comment 252) One comment argued that because tobacco manufacturers spend large amounts of money on marketing activities, changing labels is just an ordinary cost of business to them, and one that they can ''write off.'' Furthermore, the comment argued that manufacturers can, to some extent, pass the costs on to consumers. The comment ends by stating: ''It is not appropriate for the FDA to fear that its regulatory efforts on this industry might impose costs on them, and to use these costs as a reason not to proceed with its

regulations. The agency is supposed to act in the public interest, not the interest of a particular industry to protect it from protecting the public in the first place.''

(Response) The baseline expenditures of the tobacco industry are irrelevant. There is a cost to society when its scarce resources are expended to comply with this rule. The costs the comment refers to are economic or opportunity costs. Cost estimation is concerned with the value of the resources used to carry out some activity, not their incidence (*i.e.,* who ultimately pays), which is a separate question. As acknowledged in the proposed rule (section VIII.D, *Costs*), although cigarette manufacturers are legally responsible for complying with this rule, the costs may be borne at least in part by tobacco consumers. The potential for ''passing costs on'' to consumers is a matter of economic incidence but does not negate the fact that there are costs, nor does it change those costs.

In the cost-benefit analysis we estimate costs and benefits that accrue to citizens and residents of the United States (Ref. 103) regardless of who we think may bear them. The ''interest of a particular industry'' is a subject we rightly leave to the ''Distributional Effects'' section of our analysis.

(Comment 253) A comment stated that FDA should estimate ''the *marginal* cost of changing the warning labels that the cigarette companies would incur accounting for ongoing expenses associated with producing cigarette packages and assuming that the companies implemented the new labels using economical strategies.''

(Response) The labeling cost model's baseline already accounts for ongoing expenses associated with producing cigarette packages. Manufacturers change product labels at regular intervals without regulatory changes in labeling requirements. Based on both product type and compliance period, the model provides an estimate of the percent of UPCs that can be coordinated with a previously scheduled labeling change. For those UPCs, the only costs assumed by the model are a small fraction of the administrative labor cost and recordkeeping costs.

If anything, this approach taken by the model quite possibly understates the labeling costs for so-called coordinated UPCs. For example, even though a graphic designer can redesign a label to satisfy both regulatory and nonregulatory goals at once, such a redesign would plausibly take longer than a redesign to satisfy only nonregulatory requirements, and time devoted to regulatory compliance must be taken away from other activities. However, because this rule requires a set of 9 plates for the 9 different graphic labels, we manually adjust the model to add back the 8 extra plates.

(Comment 254) A comment asserted that although there are 3,324 different UPCs, each UPC would not have to be redesigned because product varieties within a brand family share essential trade dress and package design features. The comment asserted that using a number equal to 10 percent of the number of UPCs, 332, would still result in an overestimate of costs.

(Response) Although products within a brand family share certain package design features, the packages for different UPCs still contain unique features. Thus, every individual UPC represents a separate design job. Furthermore, the labeling cost model presents an *average cost per UPC* of similar types within a product category, not the cost of changing one UPC. The model therefore accounts for the existence of brand families with similar label designs.

(Comment 255) A comment asserted that FDA overestimates production and printing costs by ''not accounting for the realities of how such work is actually done.'' The comment provided the following quote from an unknown large job printer: ''In looking at the costs associated with each label, this might be fairly accurate for 1 label, but they don't take into account the economies of scale. After the first one, the second and subsequent package costs will go down exponentially. The only costs that might remain static would be the costs of printing plates, which depending on how they print them, could be reduced if they gang run several different packages of similar production runs together on the same sheet. All the non-production costs would be amortized over the whole.''

(Response) The labeling cost model does not measure the cost of changing one label, but the average cost when a large number of labels are changed at once. Due to resource constraints, the economic cost could be higher when a large number of labels are changed at once. The comment did not provide either alternate cost estimates for FDA to consider, or potential sources for such data.

(Comment 256) A comment asserted that design costs should not be inflated due to the requirement to use nine different warnings because all warnings would occupy the same portion of each package, so the redesign would only have to be done once regardless of which warning would be used.

(Response) The comment appears to misunderstand which cost elements are affected by the need for nine labels. The term ''Design costs,'' as used in the labeling cost model, could refer to all per-UPC costs associated with a labeling change or specifically to graphic design labor costs. FDA inflated some, but not all, per-UPC labeling change costs by a factor of nine.

For graphic design labor costs, FDA agrees that the part of the package design that is under the control of the manufacturer will probably be the same regardless of which of the nine warning labels is used. Therefore, the work of designing the new package label only has to be done once for each UPC; in the cost estimates, graphic design labor costs were not inflated by a factor of nine.

Likewise, FDA assumed that the need to incorporate nine different warnings on every package would have a negligible impact on administrative labor costs, prepress labor costs, and recordkeeping labor costs. These costs therefore were not inflated by a factor of nine.

It was only for materials costs, which specifically includes prepress materials and printing plate costs, that FDA assumed costs increased by a factor of nine due to the need to incorporate nine separate warning labels. We employed this assumption because nine times as many printing plates will be needed upfront.

(Comment 257) A comment argued that some of the costs attributed to the label change would be incurred on an ongoing basis. The example provided is that printing plates wear out after a few million impressions and have to be replaced at regular intervals. The comment argued our cost estimates need to be adjusted to account for this. An analysis follows which claims to demonstrate that the average cigarette label printing plate has to be replaced every 3 weeks.

(Response) The calculation provided in the comment contains errors. Once those errors are fixed, the calculation no longer supports the assertion that printing cylinders are being constantly replaced, as discussed in the following paragraphs. Furthermore, the model accounts for possible coordination with previously scheduled labeling changes, which provides the most likely opportunity for cigarette manufacturers to avoid *some* of the incremental cost from new printing plates (cylinders). New cylinders must be engraved when a nonregulatory labeling change takes place. Given the expense of the printing cylinders, manufacturers would avoid engraving new cylinders right before a

nonregulatory labeling change. In other words, we would expect some coordination between cylinder wear out and nonregulatory changes.

Rotogravure plates are the longest lasting, good for making millions of labels. The comment assumed a life of only 3 million labels and did not justify this point estimate. For rotogravure, this estimate is too low.

In attempting to determine weekly sales per UPC, the comment divided weekly cigarette sales (in packs) by their estimate of the number of brands, not by the number of UPCs. Dividing by the number of UPCs, even under the assumption that plates wear out after 3 million labels, yields a life of 29 weeks for the average brand. Updating this analysis for the revised number of cigarette UPCs yields a life of 38 weeks for the average brand.

Additional calculations can be performed for the ''average'' brand, but it is important to keep in mind that most brands are not average. A few products will have high volume. A large number of lesser-known products will have low volume.

Because manufacturers will have to buy nine plates up front for each UPC, those nine plates would have a life of 346 weeks, or 6.6 years, based on the comment's assumptions about the life of a rotogravure plate and the updated UPC count. Manufacturers of the average product would not wear out all these plates before they changed labels again for nonregulatory reasons.

(Comment 258) Multiple comments argued that FDA should not include 10 percent rush charges in calculating the cost of changing labels in 15 months. In particular, the argument was made that cigarette manufacturers have known this was coming before publication of the final rule.

(Response) Although it is true that manufacturers have known this rule was coming, in some form, since the passage of the Tobacco Control Act, it is only with the publication of the final rule that they will know its exact form, *i.e.,* what the images will be. Tobacco companies will need to see the final images and the exact provisions of the final rule before the bulk of the work for a labeling change can be undertaken.

In evaluating the need for rush charges, it is important to keep in mind that the labeling model is designed to measure the cost of changing a large number of labels at once. Resources are scarce and a large number of labeling changes cannot be simultaneously rushed without increasing costs.

The previous labeling cost model assumed 10 percent rush charges for compliance periods shorter than 2 years. The new labeling cost model assumes constant rush charges equal to 40 percent for compliance periods of 3 to 15 months. In reality, rush charges are likely to decline continuously as the compliance period increases. The rush charges under a 3-month compliance period could exceed 40 percent, and the rush charges for a 15-month compliance period are likely to be far less. FDA has therefore retained the original assumption of 10 percent rush charges for a 15-month compliance period.

(Comment 259) One comment stated that FDA has underestimated costs because of technical implementation difficulties associated with providing for equal, random, simultaneous display of nine different images.

(Response) FDA does not agree that there is a technical infeasibility. Similar requirements have been successfully implemented in other countries. The cost analysis for the label change includes administrative labor and recordkeeping costs, part of which would be associated with devising and implementing a method for ensuring equal random display. However, FDA is now persuaded that there will be some ongoing cost associated with equal, random display. In other words, once a system for compliance is designed and implemented, it will require some work to ensure continuing compliance with equal, random display. Therefore, in the Final Regulatory Impact Analysis FDA has added recordkeeping costs and administrative costs as ongoing costs in years 2 through 20 after the final rule takes effect.

(Comment 260) Comments argued that market testing costs undertaken by the tobacco industry should not be counted. Various arguments were presented: Such costs would be beyond the minimal cost required to implement the law ''effectively and in good faith.'' Such costs would be incurred in order to ''undermine the effect of Congressionally-mandated warning labels.'' Such costs would not be societal costs at all, but distributional effects because the cost to the tobacco companies would be a benefit to employees or contractors paid to do the work. If FDA includes market testing costs, it should also include legal fees for potential challenges to this rule and lobbying fees to get the statute repealed.

(Response) We do not simply estimate the cost of minimal compliance. In benefit-cost analyses of regulations, we assume agents react to a new regulation by changing behavior in many ways. The analysis itself then compares the expected outcomes with and without the rule. Regardless of whether the rule requires it, if manufacturers conduct market testing as a direct result of this rule, the costs are attributable to this rule. Resources devoted to this market testing have an opportunity cost, so there is a social cost. We have been unable to obtain reliable data with which to quantify potential costs incurred to challenge the rule in litigation. Lobbying costs associated with the repeal of the statute do not represent incremental costs of this rule and therefore are appropriately excluded from the analysis.

(Comment 261) A comment stated that cigarette manufacturers and retailers change advertisements and labels frequently and only the incremental cost of replacements that would not have otherwise been made should be attributed to this rule. The comment asserted that this incremental cost is negligible.

(Response) FDA only looked at the cost of removing point-of-sale advertisements. Other forms of cigarette advertisements are now relatively rare. The comment assumes that some or all manufacturers and retailers could perform the removal of noncompliant point-of-sale advertising at zero cost by coordinating it with the usual replacement schedule for point-of-sale advertising. Manufacturers and retailers would only remove noncompliant advertising early if the benefit from keeping them longer did not justify the modest cost (between $12 and $198 per establishment) of removing the advertising at the deadline. FDA expects that the most likely response will be for most establishments to continue displaying noncompliant advertisements up until the enforcement deadline and resources will therefore be expended to achieve compliance at the deadline.

(Comment 262) One comment stated that the cost analysis needs to include reduced government revenue from lost taxes due to lowered cigarette sales.

(Response) FDA notes that, leaving aside potential deadweight loss, there are two principal effects of tax reductions: Gains to former payers and losses to former recipients. Because these effects exactly offset each other, there is no net social cost or benefit associated with the reduction in excise tax collections induced by the rule. As such, we discuss rule-induced changes in tax collections in the Distributional Effects section of our analysis (section XI.G.5 of this document).

(Comment 263) One comment stated that the disturbing nature of the graphic warning labels will cause adverse mental reactions in those who view them, especially cashiers at cigarette-

selling retail establishments because they must handle these products daily.

(Response) FDA is not aware of any scientific evidence that mental or emotional costs would be incurred by the general public as a result of this regulation, and the comment did not provide any.

5. Distributional Effects

In the analysis of the proposed rule, FDA estimated a variety of effects that are experienced as transfers away from some segments of society and as roughly equal transfers to other segments of society. FDA received several comments about these distributional effects.

(Comment 264) One comment stated that FDA's preliminary analysis of the rule's effect on tax collections ignored offsetting effects due to increased sales of other taxable goods and services even though the Joint Committee on Taxation estimates this offset at 25 percent of a policy's direct effect.

(Response) FDA agrees with the comment and has adjusted its analysis of rule-induced changes in tax collections accordingly.

(Comment 265) One comment stated that, in its preliminary analysis of the rule's impact on tax collection, FDA suggested that inelastic demand for cigarettes means that some or all lost tax revenue could be offset through higher tax rates. The comment went on to note that FDA undertook no analysis of whether State and local governments could or would increase excise taxes on cigarettes in response to the graphic warning label rule and that the political environment, as demonstrated by recent elections, may not be amenable to tax increases.

(Response) FDA did not claim any increases in State or Federal cigarette taxes are likely to occur. Instead, we merely pointed out that cigarette demand has been shown to be inelastic; therefore, an increase in tax levels will increase revenue. For the final analysis, we have removed some of our more confusing language on this issue. We continue to assume that tax rates will rise at the rate of inflation because, without such an assumption, we need a reliable forecast of inflation in order to express the stream of future tax revenue changes in current dollars. However, we have added discussion of alternative approaches, including the possible forecasting of inflation using the difference between interest rates for Treasury Inflation-Protected Securities (TIPS) and standard Treasury bills.

(Comment 266) One comment stated that, to the extent that State and local excise taxes are based on the price of cigarettes, increased price competition that could result from the proposed rule would reduce tax revenues beyond what FDA reports in its analysis.

(Response) At present, all State and Federal cigarette taxes are applied per unit, not ad valorem; therefore, changes in the pre-tax price of cigarettes will not change the total excise tax collection separately from changes caused by decreases in the quantity sold. Sales taxes, on the other hand, are applied to cigarettes on the basis of price. FDA has not quantified the effect of the rule on sales tax collections, but we expect it to be small, both because sales taxes make up a very small portion of total cigarette-related tax collections and because any rule-induced change in cigarette prices is also likely to be small.

(Comment 267) One comment stated that, in its preliminary analysis, FDA failed to note that research indicates that U.S. employment will increase if smoking decreases.

(Response) In the PRIA (sectionVIII.F.2), FDA stated that decreases in smoking may cause increases in national employment, citing (Ref. 122) the same paper to which the comment refers.

(Comment 268) One comment stated that FDA, in its preliminary analysis, estimated that the proposed rule would result in 500 to 600 displaced jobs among manufacturers, warehouses and wholesalers but failed to note that these lost jobs probably would occur during a period of high unemployment, when the displaced individuals would likely have difficulty obtaining new jobs with similar remuneration. The comment went on to state that the average unemployment duration in November 2010 was 34.5 weeks and that one could, by multiplying the average wage by the average duration of unemployment, obtain a rough estimate of lost wages.

(Response) The wages lost are not the appropriate cost to attribute to the rule; instead, we must include the difference between wages lost from tobacco-related jobs and the value of next-best options. FDA is unable to quantify this difference. For instance, average unemployment tenure from late 2010 would likely give a skewed estimate of length of rule-induced unemployment because compliance with the rule is not required until 2012. Unemployment may change substantially between now and then, especially because the United States is currently in the early stages of recovery from a recession.

(Comment 269) One comment stated that manufacturing, warehouse, and wholesaler jobs displaced by the rule would be permanent losses to the economy. In addition to failing to note this permanence, FDA did not account for any job losses in the retail sector. The comment went on to state that convenience stores are highly dependent on tobacco sales, both in terms of cigarette sales' portion of profit margins and as a generator of customer traffic to spur the sale of ancillary products. Even the small reductions in revenue caused by the graphic warning label rule could cause retailers to reduce employment, with some stores possibly going out of business entirely.

(Response) The portion of dissuaded smokers' budgets that would, in the absence of the rule, have been spent on cigarettes will, in the presence of the rule, be spent on other goods and services, thus creating jobs in other segments of the economy. Only the difference between losses borne by individuals losing cigarette-related jobs and gains realized by individuals obtaining employment in other sectors represents a net social cost. FDA believes this difference to be small and possibly negative (that is, the losses are less than the gains), as found by Warner *et al.* (Ref. 122).

(Comment 270) One comment stated that, in its preliminary analysis, FDA incorrectly concluded that there would be no rule-induced losses experienced by tobacco growers. The comment went on to state that FDA's assumption that acreage taken out of tobacco production could be easily shifted to other crops, with no net loss, is not consistent with economic theory because economic theory indicates that land currently planted in tobacco is being used in its highest-valued use. Another comment suggested that FDA work with the Department of Agriculture on estimating the impact of the rule on tobacco farmers.

(Response) FDA agrees that a transition from tobacco cultivation to the next-best option entails some loss for farmers, but only the difference between first- and second-best uses of land represents a net social cost in terms of reduced efficiency.

(Comment 271) One comment stated that the requirement that cigarette manufacturers print half of their packaging with images supplied by the government would be a burden to all cigarette companies, the costs of which would ultimately be paid by consumers.

(Response) FDA has estimated the cost to cigarette producers of adding graphic warning labels; however, we have not assessed whether cigarette consumers or shareholders of cigarette-producing firms will bear the burden of the cost. We expect that the costs will be shared by consumers and producers but we are unable to estimate the

portions borne by each group. In the cigarette market, increases in variable costs are borne almost entirely by consumers. In the case of the addition of graphic warning labels, however, most of the cost does not vary with the quantity of cigarettes produced. We therefore expect that producers will be unable to pass all of the cost on to consumers through increased prices. Consumer prices could, however, be affected in the long run. For example, one possibility is that some cigarette product lines will be discontinued and this decrease in supply would lead to increased prices paid by consumers. FDA lacks the detailed market data that would be necessary for predicting which of these or other possible outcomes would likely be realized.

(Comment 272) One comment argued that retailers must lose profit when reallocating space away from cigarettes to other products because it was suboptimal to make such an allocation in the absence of the rule.

(Response) This comment ignores the fact that the final rule will reduce demand for cigarettes and increase demand for other products. While it is clear by observation that allocating shelf space away from cigarettes to other products *in the absence of this rule* would be suboptimal, this need not imply that retailers' profits will be lower after they optimally respond to changes in the demand for cigarettes and the demand for other products.

(Comment 273) Some comments argued that retailers (including small retailers such as convenience stores) may not be able to simply shift shelf space to other goods.

(Response) FDA argued in the distributional effects section of the proposed rule, section VIII.F.3, that the retail sector (as a whole) will shift shelf space to other products to take advantage of the increase in demand for noncigarette products. FDA acknowledges that this substitution may not take place wholly within each retail establishment. If cigarette-reliant retailers have some (but less than complete) success shifting shelf space to take advantage of the increase in demand for noncigarette products, they will suffer an overall loss in revenue that is less than their loss of cigarette sales revenue. Other parts of the retail sector would gain sales. This would be a purely distributional effect within the retail sector. Such an effect would be small because this rule is only projected to reduce cigarette consumption by less than one quarter of a percent.

6. Impact on Small Entities

In the initial regulatory flexibility analysis, FDA considered the potential effects on small cigarette manufactures of having to change all cigarette labels in accordance with this rule. FDA also considered the potential impact on small retailers of having to remove noncompliant point-of-sale advertising. FDA received comments from industry pertaining to these matters, which are summarized in the following paragraphs.

(Comment 274) A comment stated that FDA ''grossly underestimates'' costs, referring specifically to the estimates of the label change costs and their impact on small manufacturers. The comment argued that the necessary changes will cost at least $500,000 to $1 million, including such factors as package redesign, dye cuts, and the number of colors needed for the artwork. Further, ''these changes represent global changes for the manufacturers' products, and that change will have a far greater effect on the small manufacturer as opposed to larger entities.'' Many aspects of compliance will require the work of outside contractors.

(Response) It is not clear whether the comment intends to argue that the cost is on average $500,000 to $1 million *per UPC,* when many UPC labels are being changed at once, or that the total cost would be at least this much per firm, among some subset of small manufacturers. FDA does not agree that the average cost per UPC could be nearly this high. Although FDA estimates much higher total costs for the average small manufacturer, $500,000 to $1 million could describe the total costs for a subset of especially small manufacturers.

The cost estimate with which the comment takes issue was based on a combination of the old FDA labeling cost model and early estimates of some values from the new FDA labeling cost model. Costs have been updated in the analysis for the final rule to more fully reflect the estimates of the new model. Interviews with manufacturers and trade associations were conducted in the process of building the new model. FDA believes the model provides the best estimate of the average cost of changing a product label. FDA inflates materials costs by a factor of nine to account for the requirement to use nine separate warnings.

The comment also argued that FDA has underestimated the costs to small businesses but is not specific enough about whether there are additional factors, beyond the results of the labeling cost model, with which the comment disagrees.

FDA agrees that small tobacco product manufacturers are more likely to hire outside contractors for tasks required to comply with this rule. However, from a societal point of view, it makes no difference to costs whether a manufacturer conducts the functions required for compliance in-house or contracts them out.

(Comment 275) A comment argued that small manufacturers do not carry a small inventory of supplies, but must buy materials in bulk to be cost effective (often as much as 6-months worth). The comment stated therefore that it is untrue that all label inventories will be exhausted during the 15-month compliance period. Small manufacturers will have to discard large amounts of advertising and labeling material. Another similar comment argued that small manufacturers purchase long-term quantities of ''advertising pieces such as pole signs and shelf talkers,'' in order to get better prices. FDA should take this into account and give small manufacturers time to use up existing inventories of printed materials. The comment suggested that manufacturers could provide FDA with inventory counts and usage rates.

(Response) FDA believes the first comment combines two separate issues: Label inventory assumptions (the matter at hand in the quote from the preliminary analysis) and advertising inventory assumptions.

FDA stands by its conclusion that the costs of discarded label inventory will be small under a 15-month compliance period. With modern just-in-time inventory control methods, firms keep far less inventory on hand than in decades past. However, rather than assume that there is zero cost for discarded inventory, FDA will accept the new labeling cost model's default assumptions regarding discarded inventory. This assumption results in a low inventory cost being attributed to this final rule, as very little inventory is expected to remain after a 15-month compliance period. While it may be the case that some small manufacturers keep large amounts of inventory on hand, the evidence used to construct the labeling cost model implies that most manufacturers would not have much (if any) label inventory remaining after 15 months and the output of the labeling model accurately represents the average inventory cost.

While it is possible that some manufacturers will have some point-of-sale advertising materials in inventory that will be discarded as a result of this

rule, FDA doubts that this inventory cost is substantial. Manufacturers will have 15 months to use up existing inventory. Cigarette manufacturers are known to be sophisticated advertisers, and effective advertising changes to reflect the times. Therefore, the value of existing advertisements would decline over time as they become more dated and less effective. Additionally, the comments themselves do not provide data with which to estimate any effect that may exist.

(Comment 276) One comment estimated that the label change cost would be between $2.1 million and $5.5 million per average small tobacco product manufacturer, based on an average number of UPCs per firm of 44. The comment asserted that small manufacturers cannot absorb the cost of changing all their cigarette labels and many will leave the cigarette manufacturing business. Two relief options were suggested: Phasing in the rotational warnings over a longer period of time or running the warnings sequentially rather than simultaneously.

(Response) According to this comment, small tobacco product manufacturers have fewer UPCs each than FDA originally estimated. If the UPC estimate from the comment holds, the compliance costs for small firms would be lower than FDA originally estimated. FDA has retained the original method for estimating the number of UPCs for small firms so as to take care not to understate the burden on them.

FDA acknowledges that this rule may put some small manufacturers at risk of going out of business. However, we do not have the information necessary to estimate this risk. In the initial regulatory flexibility analysis, FDA considered the relief that would be provided by allowing small (or all) tobacco product manufacturers additional time to comply with the rule, even though this not in keeping with the statutory mandate. Running nine warnings sequentially rather than in parallel is a complicated alternative for which it is difficult to estimate the amount of relief provided. A very large reduction in costs would only materialize if the warnings were only changed as often as the usual frequency of nonregulatory label changes (every couple of years). However, FDA has now included an analysis of the potential impact of a related relief option, that of letting small manufacturers randomly assign one label to each distinct UPC.

(Comment 277) Some comments argued that some small retailers, such as convenience stores, may go out of business as a result of reduced cigarette sales and loss of revenue from ancillary products, and that this effect of the rule on small entities needs to be reflected in the analysis. Beyond the effect on the retailers themselves, closure of convenience stores would result in loss of convenience to nearby customers and could also adversely affect suppliers.

(Response) Although in the small entity analysis we are only able to quantify the cost of removing noncompliant advertising, we acknowledge that small retailers selling cigarettes could also lose some net sales revenue (to other retailers), to the extent that shifting shelf space to other goods less than fully offsets the reduction in revenue from cigarettes. We expect any such loss of revenue to be modest because the expected reduction in cigarette consumption is modest to begin with. Convenience store closures as a result of this final rule are therefore unlikely.

(Comment 278) One comment recommended that FDA reconsider exempting small cigarette producers.

(Response) The initial regulatory flexibility analysis considered exempting small manufacturers from the label change requirements as a relief option. Exempting small manufacturers from all or part of this regulation would cause a significant proportion of consumers to be exposed to cigarette packages or advertising lacking the new graphic warnings. In 2008, the combined market share of all but the four largest firms was 10.3 percent (Ref. 123). This situation would be inconsistent with the public health objective of the rule as well as FDA's statutory mandate.

C. Need for the Rule

Written with the goal of ameliorating the large toll on public health that is directly attributable to the consumption of tobacco, the Tobacco Control Act mandates the publication of this rule. Section 201 of the Tobacco Control Act modifies section 4 of FCLAA to require that nine new health warning statements, along with color graphics depicting the negative health consequences of smoking, appear on cigarette packages and in cigarette advertisements. As discussed in detail in FDA's response to comments in section XI.B.2 of this document, the economics literature suggests several sources of market failure [11] that the new graphic warning labels will address; these include myopia, lack of salience, time inconsistency, and incomplete information. In the following analysis, we do not attempt to choose among the many models of smoking and addiction that potentially cause market failure, but the models have similar policy implications.

D. Benefits

We estimate the benefits of the final rule by comparing expected life-cycle events of smokers with those of nonsmokers. Nonsmokers tend to live longer and develop fewer cancers, cardiovascular, pulmonary, and other diseases, so the benefits in our analysis include the discounted value of life-years gained, health status improvements and medical services freed for other uses. We also include an estimate of the monetary value of the property and lives saved as a result of the rule-induced reduction in the number of accidental fires caused by smoking. There are other benefits, such as reductions in nonsmokers' morbidity and mortality associated with both passive smoking and mothers smoking during pregnancy, that are likely generated by the final rule, but FDA has been unable to obtain reliable data with which to quantify them. In particular, we were not able to project future levels of exposure to secondhand smoke from historical trends, nor predict future decreases in maternal smoking during pregnancy.

1. Reduced Cigarette Smoking Rates

The changes outlined in this rule are projected to decrease smoking initiation and increase smoking cessation. For each of the first 20 years of the rule's implementation (2012 through 2031),[12] FDA calculates the predicted decrease in the number of U.S. smokers by multiplying together the following:

(a) The estimated effect (percentage point change) of cigarette warning labels on the national cigarette smoking rate and

(b) The population in a particular year in the absence of the regulation (as projected by the U.S. Census Bureau).

To obtain estimates of the effect of cigarette warning labels on smoking rates (item (a) in the list above), we look to the experience of Canada, which has required the use of graphic warning labels since December 2000 (Ref. 124). The advantage of this approach lies in our ability to observe actual consumer behavior—in the form of smoking rates—before and after a graphic warning label requirement went into

[11] A situation in which a market left to itself does not allocate resources efficiently.

[12] The effects of antismoking policies occur over a long period of time, so we want to include at least one full generation in our analysis. Using a 20-year time horizon allows us to do this while still avoiding the extreme uncertainty regarding effects occurring in the more distant future.

effect. The warning labels to be required in the final rule are generally similar to those developed by Health Canada and authorities in other foreign countries. As in Canada, the labels required by the rule will occupy at least half the front and rear display panels of a cigarette package. Moreover, under the rule, there will be a mix of warning statements and images that depict the negative consequences of smoking. Although the rule will follow much the same approach as the Canadian warning label requirements, it will differ in some ways: Canada has 16 labels in rotation, rather than 9; warning statements appear in English on one side of a Canadian package and in French on the other; and health and cessation information is included on leaflets within Canadian cigarette packages (Ref. 125). These details, combined with general differences in legal and social trends, indicate that Canada's experience with warning labels can give only a general idea of the changes in smoking rates to be expected as a result of the rule. In addition, other smoking control initiatives, including new restrictions on smoking in indoor public places, also occurred in both the United States and Canada during the period of our analysis. These and other confounding factors make our estimate of the effect of new graphic warning labels highly uncertain.

Health Canada (Refs. 126 and 127) reports Canadian smoking rates for ages 15 and above for years from 1994 through 2009. FDA obtained smoking rates for adults, aged 18 and above, in the United States from the National Health Interview Survey (Ref. 128) and from ''Health, United States, 2005,'' published by the National Center for Health Statistics (Ref. 129). We used the results from these two reports to calculate the United States-Canada smoking rate difference for individual years. As shown in table 4 of this document, the smoking rate in Canada was, as of the most recent survey estimates, more than three percentage points lower than the rate in the United States and approximately seven percentage points lower than Canada's own smoking rate in the year before graphic warning labels were implemented in that country. It would be unjustified, however, to conclude that the introduction of graphic warning labels in the United States will cause the U.S. smoking rate to fall by seven, or even the three percentage points needed to reach the Canadian rate. Many factors, such as tobacco advertising restrictions, youth access restrictions, educational campaigns regarding the health effects of smoking, restrictions on smoking in indoor public places, and taxes on tobacco products have influenced smoking rates in the two countries. In order to estimate the incremental effect of the present rule, we need to isolate the impact of graphic warning labels on the Canadian smoking rate.

In order to accomplish this, as discussed in detail in Technical Appendix X1, we begin by using data from Health Canada (Refs. 126 and 127), the National Center for Health Statistics (Ref. 129), and the National Health Interview Survey (Ref. 128) to estimate pre-2001 smoking rate trends for both the United States and Canada. Because tax-induced changes in the price of cigarettes have been shown to substantially reduce smoking, in each trend estimation we include the effects of Federal and State or provincial cigarette tax changes on national smoking rates. (After decreasing substantially in the early 1990s, Canada's real average cigarette excise tax level grew by 9 percent between 1995 and 2000 and by 123 percent between 2001 and 2009. Real average cigarette tax levels in the United States grew by 29 percent between 1995 and 2000 and by 117 percent between 2001 and 2009.) Using the estimated trends, we predict smoking rates for the United States and Canada, and the difference between them, for years up to and including 2009. We then subtract the predicted United States-Canada smoking rate differences from the actual differences observed in the data. Implicit in this method is the assumption that these otherwise-unexplained differences may be attributed solely to the presence in Canada of graphic warning labels. We do not account for potential confounding variables or for possible substitution by consumers from cigarettes to other products (such as little cigars) that may produce similar health effects; our method is therefore a rudimentary approach to estimating the smoking reduction that will be effected by the new graphic warning labels and may be producing results that are off by one or more orders of magnitude.

Table 4.--Cigarette Smoking Rates, United States and Canada, 1991-2009

Year(s)	Smoking Rate, Canada[a]	Smoking Rate, United States[b]	Year(s)	Smoking Rate, Canada[a]	Smoking Rate, United States[c]
1991	31.1		2001	21.7	22.6
1994-95	30.5		2002	21.4	22.3
1995		24.6[c]	2003	20.9	21.3
1996-97	28.6		2004	19.6	[e]
1997		24.6	2005	18.7	20.7
1998		23.9	2006	18.6	20.6
1998-99	27.7		2007	19.2	19.4
1999	25.2	23.3	2008	17.9	20.4
2000	24.4	23.1	2009	17.25[d]	20.5

[a] Source: Health Canada (Ref. 127), unless otherwise noted. Canada's reported smoking rates are for ages 15 and above.
[b] Source: FDA analysis of National Health Interview Survey (Ref. 128), unless otherwise noted. Reported smoking rates for the United States are for ages 18 and above.
[c] Source: National Center for Health Statistics (Ref. 129). Reported smoking rates for the United States are for ages 18 and above.
[d] Health Canada (Ref. 126) reports a smoking rate of 17 percentage points; this could be rounded from any value between 17.0 and 17.5, so FDA uses the midpoint of 17.25.
[e] The Sample Adult file of the 2004 NHIS lacks the stratum and primary sampling unit variables necessary for calculating sample statistics.

Using this rudimentary approach, FDA estimates that the average unexplained difference between United States and Canadian national smoking rates is 0.088 percentage points higher for the 2001 through 2009 period than for 1994 through 2000. Applying this estimate to population projections (Ref. 130 provides annual projections only through 2030, so we assume cohort populations will remain the same from 2030 to 2031); summing over all age groups yields an estimate that the rule will reduce (either through cessation or avoided initiation) the United States' smoking population by approximately 213,000 in 2013, with the total decrease rising to approximately 246,000 in 2031 due to the predicted smoking rate decrease being applied to a growing population. FDA has not quantified rule-induced decreases in cigarette consumption among smokers who do not quit entirely, although such decreases have the potential to improve health outcomes for affected individuals.

2. Quantifying Benefits That Accrue to Dissuaded Smokers

a. *Smokers' willingness-to-pay for cessation programs.* One method for estimating dissuaded smokers' net internal benefits involves using the amount smokers are willing to pay to participate in cessation programs. This willingness-to-pay will equal the value of cessation (*i.e.,* the value of health and other benefits of cessation minus any value that smokers attribute to the activity of smoking) multiplied by the participation-related probability of success. Warner *et al.* (Ref. 131) report that the choke price, or the price at which no smokers would participate in cessation programs, may be around $350 (in 2000 dollars), while a maximum of 10 percent of the smoking population would participate in cessation programs even if those programs had a money price of zero. With a linear demand curve, these parameters produce an average willingness-to-pay among potential cessation program participants of $175. Warner and coauthors report that approximately 15 percent of smoking cessation program participants successfully quit without eventual relapse. These parameters indicate that the average value of cessation is $175/0.15 = $1,167, or $1,444 when updated for inflation (using Ref. 132).

We estimate in section XI.D.1 of this document that the final graphic warning label rule would reduce the U.S. adult smoking population by 213,000 in 2013. In the absence of the rule, the baseline 2013 smoking population would be approximately 49.5 million, so a decrease of 213,000 represents a 0.43 percent effectiveness of graphic warning labels. The value to an individual smoker of graphic warning labels equals their effectiveness multiplied by the value of cessation, or 0.0043*$1,444 = $6.22. Multiplying by the predicted 2013 smoking population yields an aggregate value of the rule of $6.22*49.5 million = $307.9 million. For each year from 2014 to 2031, we perform an analogous calculation, but we replace the entire smoking population with only the particular year's newly exposed cohort (consisting of 18-year-olds and new immigrants). This results in a present value of net intrapersonal benefits of $370.3 million, calculated with a 3-percent discount rate, or $322.4 million, calculated with a 7-percent discount rate.

While these values can provide rough estimates of the benefits of the final rule, there are several reasons to believe they are only approximations and probably reflect lower bounds. First, we are implicitly assuming that the value of avoided smoking initiation is equal to the value of cessation and that the value of cessation is equal across the entire smoking population. In fact, we have willingness-to-pay data only from those smokers who are potential participants in cessation programs. The value of avoided initiation is likely much higher than the value of cessation, which would tend to make the present estimates of rule-induced benefits too low. A second reason willingness-to-pay for cessation programs represents a lower bound on the rule's benefits is because it captures only the misinformation and time-inconsistent preferences that smokers themselves recognize and act upon via participation in cessation programs.

b. *Gross and net health benefits.* We now turn to the literature on time inconsistency, which is one of the principal forms of market failure relevant to tobacco, to develop an alternative approach to estimating rule-induced benefits that accrue to dissuaded smokers. The papers we will

discuss use the term ''optimal internality tax,'' but the key point is that taxes and cessation programs are both tools that cause a reduction in smoking, and the dollar prices of those tools represent estimates of the amounts that smokers would be willing to pay to gain the net intrapersonal benefits associated with smoking reduction.

Gruber and Köszegi (Ref. 104) estimate the tax rate that would allow time-inconsistent smokers to consume the quantity that would be optimal under perfect rationality and in the absence of other forms of market failure. They first estimate an internal health cost of $30.45 per pack. From this cost, they calculate an internality tax that ranges from $0.98 to $2.89 (depending on technical parameters of their model), with an average of $2.17. Because the demand for smoking is downward-sloping, a decrease in the smoking rate will decrease the optimal internality tax. In Technical Appendix X5, we account for this complication. Because we find that Gruber and Köszegi's results imply that net internal benefits of the rule equal roughly 7 (=100 − 93) percent of the gross internal (health) benefits, the average optimal tax over the relevant portion of the demand curve is 0.07*$30.45 = $2.05 per pack. Multiplying this optimal tax by the predicted rule-induced reduction in cigarette consumption would yield an estimate of benefits that accrue to dissuaded smokers.

In other writings, Gruber (Ref. 133) suggests that, because his work with Köszegi considered only a limited degree of time inconsistency, the optimal internality tax on cigarettes could be much higher than the level estimated with Köszegi, perhaps between 5 and 10 dollars per pack. (Even this amount does not, however, account for other forms of market failure that might be relevant to tobacco use.) The midpoint of the 5 to 10 dollar range, $7.50, yields a net internal benefits result equal to roughly 24 percent of rule-induced internal health benefits. Other models of addiction and smoking would imply different net internal benefits, depending on the implied severity of the market failure. One comment on the proposed rule, from a scholar who has done a great deal of professional research on the economics of smoking, suggested that smokers would assess the value of quitting smoking as 90 percent of the value of health gained from smoking. Although this and other public comments suggested high ratios of net to gross health benefits, none provided evidence supporting their suggestions.

The applicability of any of the suggested net-to-gross internal benefits ratios requires an estimate of the gross benefits realized by individuals who are dissuaded from smoking. Gruber and Köszegi admit that their $30.45 per pack estimate is not exhaustive, so we now turn to quantifying morbidity, mortality, and other effects of smoking cessation and avoided initiation.

i. *Expected life-years saved.* The largest health consequence of smoking is the increased rate of mortality from pulmonary and cardiovascular disease, cancer, and certain other illnesses. As a result, the largest benefits of this rule stem from the increased life expectancies for those individuals who, in the absence of the rule, would be smokers and thus susceptible to premature mortality from one of these often-fatal diseases. We calculate the number of life-years saved using differences in the probabilities of survival for smokers and nonsmokers. Sloan *et al.* (Ref. 116) construct life tables for various categories of individuals, including ''nonsmoking smokers'' and typical 24-year-old smokers. A nonsmoking smoker is someone who does not use cigarettes but otherwise exhibits the lifestyle and personal characteristics of the average smoker.[13] A typical 24-year-old smoker does not necessarily smoke for his or her entire life, but instead faces cessation probabilities that are in line with values observed for all ages in the National Health Interview Survey; the life expectancy effects of cessation at older ages are netted out of life expectancy effects of avoiding smoking at age 24 (results reported below). Sloan *et al.'s* life tables allow us to calculate how many additional deaths, per 100,000 population, may be expected among typical smokers than among nonsmoking smokers between the 24th and 25th birthdays, the 25th and 26th, and so on until the 100th birthday. (FDA assumes that differences in yearly survival probabilities for smokers and nonsmokers are negligible below age 24 and above age 100.)

Overall, Sloan *et al.* find that an average (or what Sloan *et al.* call ''typical'') 24-year-old female smoker can expect to live another 55.5 years, while a comparable nonsmoker can expect another 57.8 years of life, producing an overall regulation-induced gain of 2.4 undiscounted life-years per individual who is prevented from starting to smoke. Comparing male 24-year-old typical and nonsmoking smokers, life expectancy increases from 49.8 to 54.2 years, producing a gain of 4.4 undiscounted years. The gap between male and female life expectancy results may be due to different physiological responses to equal amounts of smoking, different lifetime cessation patterns, or different smoking intensities. Taylor *et al.* (Ref. 117), for instance, find that male smokers are more likely than female smokers to consume more than a pack a day. Sloan *et al.* do not report how much of the male-female difference in their estimated life expectancy effects may be attributed to each possible mechanism. In spite of this limitation, FDA considers Sloan *et al.'s* methodology to be the most suitable in the literature for purposes of the present analysis due to other studies' omissions of a nonsmoking smoker adjustment, a lifetime cessation probability adjustment, or both.

We assume that each person who reaches ages 18 to 24 during the 20 years (2012 to 2031) of our analysis and is dissuaded from smoking extends his or her life by the gender-specific amount Sloan and coauthors report. For older individuals, whose post-smoking cessation survival probabilities cannot be plausibly assumed to equal those of individuals who were nonsmokers at age 24, we predict life extensions using former smoker life tables that we construct using Sloan *et al.'s* results and cessation probabilities from the 1998 National Health Interview Survey (Ref. 128). The details of these adjustments appear in Technical Appendix X2.

ii. *Benefits of reduced premature mortality.* OMB Circular A–4 (Ref. 103) advises that the best means of valuing benefits of reduced fatalities is to measure the affected group's willingness-to-pay to avoid fatal risks. Three life-year values (also known as values of a statistical life-year, or VSLY) used frequently in the literature and in previous analyses are $100,000, $200,000, and $300,000 (Refs. 134 and 135; 74 FR 33030, July 9, 2009), which we update to $106,308, $212,615, and $318,923 in 2009 prices. These values constitute our estimates of willingness-to-pay for a year of life preserved in the present. The economic assessment of a future life-year requires discounting its value to make it commensurate with the value of present events. As required by OMB Circular A–4, we use 3-percent and 7-percent discount rates to calculate the present value of the life-years we predict will be saved.

For each dissuaded smoker, we multiply a VSLY by the relevant age- and gender-specific life extension and

[13] In their multivariate regression analysis, Sloan *et al.* control for alcohol intake, body mass index, financial planning horizon, race, education, and marital status.

then discount appropriately to arrive at a per-person value of reduced mortality. For 24-year-olds, this value ranges from $9,280 (for a female applying a VSLY of $106,308 and a 7-percent discount rate to her 2.4 life-years gained due to smoking avoidance) to $363,333 (for a male applying a VSLY of $318,923 and a 3-percent discount rate to his 4.4 life-years gained due to smoking avoidance). Multiplying the per-person values by the predicted number of dissuaded smokers and discounting the results back to year 2011 yields estimates of rule-induced mortality benefits that range from $1.45 to $22.56 billion.

Table 5.--Gross Present Value of Lifetime Reduced Smoker Mortality ($ mil)

Value of a Statistical Life-Year = $106,308		Value of a Statistical Life-Year = $212,615		Value of a Statistical Life-Year = $318,923	
3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
7,520.9	1,450.6	15,041.7	2,901.1	22,562.6	4,351.7

These totals may understate the full value of rule-induced reductions in mortality because they do not account for increasing trends in life expectancy. Sloan *et al.*'s results, from which our mortality estimates are derived, are based on data from the late 1990s. Arias (Ref. 136) reports that between 1999 to 2001 and 2006 (the most recent year for which life tables have been developed), life expectancy at age 25 increased from 50.54 to 51.5 years, or 1.90 percent, for males and from 55.41 to 56.1 years, or 1.25 percent, for females. If these percentage changes are approximately correct for the typical smoker and nonsmoking smoker populations, then our estimates of smoking-related life expectancy effects would need to be adjusted upward accordingly (or perhaps by different percentages because life expectancy has continued to change since 2006).

A further reason to believe the values in table 5 of this document may be underestimates is their lack of quantification of any reduction in either the external effects attributable to passive smoking or the infant and child fatalities caused by mothers smoking during pregnancy. Sloan *et al.* (Ref. 116) indicate that, historically, the inclusion of spouse and infant deaths from exposure to secondhand smoke or mothers smoking while pregnant increased estimates of smoking's mortality effects by approximately 26.3 percent. We do not incorporate this adjustment into our analysis, however, because recent restrictions on indoor public smoking and educational campaigns have significantly reduced, though not eliminated, nonsmokers' exposure to secondhand smoke. In other words, an analysis of the rule's impact on health benefits that accrue to individuals other than smokers themselves requires three pieces of estimation: (1) The rule-induced change in the number of U.S. smokers, (2) the relationship between the number of smokers and exposure of nonsmoking individuals to the harmful effects of cigarettes, and (3) the effect of cigarette exposure on nonsmokers' mortality. The ever-changing level of nonsmoker cigarette exposure means that a simple extrapolation from the recent past provides a much less reliable prediction of the near future for element (2) than for other pieces of this analysis. Any estimation of (2) would therefore be highly data-intensive and subject to an unacceptable level of potential error. In general, FDA has been unable to obtain data with which to solve this problem; it is for this reason that we do not quantify health benefits that will accrue to individuals other than smokers themselves.

We do, however, note that the Robert Wood Johnson Foundation (Ref. 137) reports that the percentage of the U.S. population living in homes where smoking was permitted decreased from 56.9 percent in 1992 to 1993 to 20.9 percent in 2006 to 2007. This may indicate that the ratio of spouse and infant mortality effects (related to passive smoking) to smoker mortality effects is now approximately 36.7 (= 20.9/56.9) percent as large as the 26.3 percent ratio derived from Sloan *et al.*'s results (which were calculated using data from the 1990s). Using this very rough approximation yields a present value of spouse and infant mortality benefits ranging from $140.3 million (= 0.263*0.367*$1.45 billion) to $2.18 billion (= 0.263*0.367*$22.56 billion). Although there are serious weaknesses with this estimation approach that make it inappropriate to include in our overall benefits analysis, the results may give a sense of the magnitude of mortality benefits generated by the rule via reductions in spousal and fetal smoking exposure.

iii. *Improved health status (or reduced morbidity).* In the previous section, we estimated the benefits that will accrue as a result of the rule-induced reduction in premature deaths from cancer, pulmonary and cardiovascular disease, and other smoking-caused illnesses. Cigarette smoking also imposes costs on smokers in the form of pain, distress, and impaired function even before these illnesses cause fatalities. As with premature death, individuals are assumed to be willing to give up valuable resources in order to avoid reductions in quality of life associated with smoking-related illnesses.

Sloan *et al.* (Ref. 116) examine survey respondents' self-reported health status (which can be categorized as poor, fair, good, very good, or excellent) and estimate that a 24-year-old smoker can expect, on average, an extra 1.086 discounted years (using a discount rate of 3 percent and averaging over Sloan's estimates for males and females) or 0.521 discounted years (using a discount rate of 7 percent and again averaging over males and females) of fair or poor health over his or her lifetime, as compared with a nonsmoking smoker.

In order to quantify the value of rule-induced reductions in years spent in fair or poor health, we scale our estimates of the VSLY ($106,308, $212,615, and $318,923, as discussed in the previous section of this document) by a ratio representing the trade-off individuals are willing to make between time spent in best-possible and lesser levels of health. Nyman *et al.* (Ref. 138) estimate this trade-off by matching survey respondents' self-reported subjective health statuses with their EuroQol–5D (EQ–5D) health index scores. The EQ–5D survey responses—to questions about five areas of health, including mobility, self-care, pain, anxiety, and ability to perform usual activities—are mapped so that a score of one represents best measurable health, a score of zero represents death, and fractional values represent intermediate levels of health. Nyman *et al.*'s analysis indicates that, relative to the health index score of an individual with excellent health, a very good health score will be lower by 0.03,

a good health score will be lower by 0.078, a fair health score will be lower by 0.194 and a poor health score will be lower by 0.392. Weighting by Nyman *et al.*'s reported percentages of respondents in each health category, FDA finds that the health index score for the average individual in good, very good, or excellent health is lower than the index for excellent health by 0.036 and the health index score for the average individual in fair or poor health is lower than the index for excellent health by 0.244; the difference between these averages is 0.208. This result may be interpreted as follows: The harm experienced by an individual whose health changes, for 1 year, from good, very good, or excellent to fair or poor is equal, on average, to the harm experienced by an individual in the best possible health whose death is hastened by 0.208 years. Thus, the welfare effect of smoking-related health status changes may be found by multiplying a plausible life-year value (such as $106,308, $212,615, or $318,923) by 0.208; this multiplication yields estimates of $21,800, $43,600, and $65,400 for the amounts individuals are willing to pay to avoid a year of reduced health status.

The U.S. Census Bureau (Ref. 130) predicts that the nation's 24-year-old cohort will be 2.17 million females and 2.25 million males in 2013 and rise steadily to approximately 2.25 million females and 2.33 million males in 2031. FDA's estimate of a 0.088 percentage point reduction in the U.S. smoking rate thus translates to a decrease of 3,906 24-year-old smokers in 2013, with the decrease rising to approximately 4,154 in 2037. Multiplying these estimates of the rule-induced reduction in the number of smokers by Sloan *et al.*'s predictions of discounted reduced health-years per smoker and the quality-of-life loss per year of fair or poor health derived from Nyman *et al.,* and discounting appropriately, yields a rule-induced welfare gain of $0.5 to $4.7 billion. Detailed results appear in table 6 of this document.

Table 6.--Present Value of 24-year-olds' Lifetime Health Status Improvements ($ mil)

Value of a Statistical Life-Year = $106,308		Value of a Statistical Life-Year = $212,615		Value of a Statistical Life-Year = $318,923	
3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
1,580.7	500.5	3,161.4	1,001.0	4,742.2	1,501.5

Sloan and coauthors do not report the effect of smoking on fair or poor health years for dissuaded smokers of ages other than 24; in the absence of a reliable estimate of the morbidity effect of smoking cessation for individuals aged 25 and above, FDA takes the conservative approach of estimating benefits only for adults who are at or below that age sometime during the first 20 years of the rule's implementation. Smoking cessation brought about by this rule will improve health status, in some cases substantially, for many individuals who are over age 24 at the time of the rule's implementation. Our omission of these benefits to older individuals produces an underestimate of the rule's morbidity benefits (which is why we describe our estimate as conservative) but there are several reasons to believe the magnitude of the underestimate may not be overwhelmingly large. First, although individuals aged 24 and below make up a fairly small portion of the smokers we estimate will be dissuaded from smoking in 2013, they make up the vast majority of smokers newly dissuaded in years 2014 to 2031 because it is young people and a few immigrants who will be exposed to graphic warning labels for the first time in those later years. Overall, then, our morbidity results include effects for 98,355, or 33.8 percent, of our estimated 291,103 (undiscounted) smoking dissuasions. Second, the reduction in health risk experienced by smokers who quit at ages 25 and above will be smaller than the benefits experienced by individuals who quit at age 24 and below or who avoid smoking initiation altogether. Third, in a study conducted with a methodology very different from the one used in this regulatory impact analysis, Stewart *et al.* (Ref. 139) estimate that smoking avoidance can increase discounted life expectancy by 1.73 years and quality-adjusted life expectancy by 2.17 years; this implies that, in the realm of smoking avoidance, the magnitude of morbidity benefits is around 25 percent of the magnitude of mortality benefits. Compared with this independent evidence, FDA's morbidity results, which are 15.3 percent (undiscounted), 21.0 percent (discounted at a 3-percent rate) or 34.5 percent (discounted at a 7-percent rate) as large as mortality effects, appear to be only moderate underestimates.

iv. *Medical services.* Sloan *et al.* (Ref. 116) estimate that smokers use more medical services over their life cycles than do comparable nonsmokers, with a specific net cost of $3,757 per female 24-year-old smoker and $2,617 per male 24-year-old smoker (in 2000 dollars and with a 3-percent discount rate). Of the female smoker's net cost, $2,031 will be borne by the smoker herself and the remainder by nonsmokers in the form of increases in private insurance premiums or taxes used to fund government health programs such as Medicaid. Of the male smoker's net cost, $1,372 will be borne by the smoker himself and the remainder by nonsmokers. We adjust these cost estimates for inflation using the most recent medical care CPI (Ref. 140).

Sloan and coauthors do not report expected medical costs for former smokers, so estimating benefits for individuals aged 25 and above who cease smoking as a result of the rule requires some assumptions. For this analysis, we assume that smoking-related annual excess medical costs are the same whether smokers are compared with never-smokers or former smokers and that the payments, reported by Sloan *et al.* as present values for 24-year-olds, are distributed equally from ages 24 to 100 (in other words, we annualize Sloan *et al.*'s estimated present value over the 77 years between ages 24 and 100). With these assumptions, given FDA's projected 20-year reductions in smoking prevalence, we anticipate that the regulation will cause smoking-related medical expenditures to fall by $859.9 million, of which $458.2 million will be realized as savings by smokers themselves and $401.7 million by nonsmokers. With a 7-percent discount rate, the total decrease in expenditure becomes $491.3 million, with $261.2 million of those savings accruing to smokers and $230.1 million to nonsmokers. Further details about the nonsmoker portion of expenditures appear in the Distributional Effects portion of this analysis.

In the absence of the rule, some portion of smoking-related medical expenditures accrues to health service providers as economic rent (also known

as producer surplus [14]). Any reduction of this portion will not contribute to the social benefit of the rule but will instead be a transfer of resources from health service providers to consumers, public and private insurers, and others. A further complication in the analysis of the market for health is generated because nonsmokers' payments take the form of a subsidy for smoking-related medical services and thus some portion of their expenditure in the absence of the rule is greater than smokers' own willingness-to-pay for those medical services. Both for this reason and due to the existence of economic rent, the avoidance of at least some portion of nonsmokers' smoking-related spending will transfer value from one portion of society to another but not contribute to an overall social benefit of the rule. We do not know the size of this portion relative to nonsmokers' overall rule-induced expenditure change, so we assume that 50 percent of nonsmokers' smoking-related spending accrues as a net social benefit of the rule. This produces an overall estimate of rule-induced reductions in medical expenditures of $659.0 million, calculated with a 3-percent discount rate, or $376.3 million, calculated with a 7-percent discount rate.

v. *Other financial effects of smoking cessation.* In section XI.F.6 of this document, we will discuss in detail the effects of the rule on Social Security, income taxes, private pensions, and life insurance. Summaries of these effects will appear in table 23 of this document. For the most part, we will characterize the values appearing in table 23 as transfers, having equal and offsetting effects on various members of society. There are, however, some additional consequences of these transfers that must be considered in light of the optimal internality tax estimation approach and the related need to estimate gross internal benefits and costs of dissuaded smoking. The mixture of positive and negative values in table 23 shows that societal transfers can take the form of both subsidies and additional costs of smoking; when summed together, the positive and negative effects in table 23 show a net smoking subsidy, which individuals relinquish when they avoid initiating or quit smoking.

There is a difficulty in quantifying the effect of the types of transfers appearing in table 23 of this document on internal benefits. Smokers' experience of these transfers may already be included in the section XI.D.2.b.ii and XI.D.2.b.iii of this document estimates of gross health benefits because the willingness-to-pay measure on which we base our morbidity and mortality calculations includes all the effects a person will likely experience as a result of improving his or her health and extending his or her life. These effects include increased opportunities to collect Social Security and defined benefit pension payments, a decreased chance of leaving survivors enough life insurance to make up for the amount paid in premiums, and increases in pension and income tax payments (due to working longer and receiving higher wages in compensation for higher productivity). If the results in section XI.D.2.b.ii and XI.D.2.b.iii of this document already reflect these phenomena, what is missing from our analysis is not the intrapersonal effect associated with smokers' experience of table 23 transfers but the direct benefit to the general public of no longer providing a net smoking subsidy; in this case, the total value of the subsidy, or 100 percent of the values in table 23, would need to be added to our net benefits estimate. Because morbidity and mortality are the primary but not the only ways in which smoking affects Social Security, income tax, pension, and life insurance payments and receipts, we do not know the extent to which our morbidity and mortality willingness-to-pay measures capture smokers' experience of these transfers. We will assume that 50 percent of the midpoint values in table 23 are included in our morbidity and mortality estimates; with this assumption, our estimated net benefits will change in two opposing directions: They will increase by 100 percent of the midpoint values in table 23 (representing the reduced subsidy payment from the general public), but will decrease by an amount equal to 50 percent of the table 23 midpoint values times the net-to-gross benefits ratio (representing the effects on dissuaded smokers that are not included in the morbidity and mortality estimates).

Summing our estimates of rule-induced life-year extensions, health status improvements, medical cost reductions, and financial effects, we find that the present value of health-related and financial benefits accruing to dissuaded smokers totals $9.29 to $27.50 billion (with a 3-percent discount rate) or $2.10 to $6.01 billion (with a 7-percent discount rate). As shown in table 7 of this document, the present value of financial benefits accruing to the general public totals $733.1 million (with a 3-percent discount rate) or $330.3 million (with a 7-percent discount rate).

Table 7.--Financial Benefits Accruing to General Public ($ million)

	Discount Rate = 3%	Discount Rate = 7%
Smoking-Related Medical Cost Subsidies, Net of Reduced Producer Surplus for Health Care Providers	200.9	115.0
Social Security Outlays	-649.2	-263.2
Income Taxes on Social Security-Taxable Earnings	746.5	301.5
Defined Benefit Private Pension Outlays	-906.8	-366.1
Life Insurance Outlays	1,341.7	543.1
Total	733.1	330.3

Note: Positive entries in the table represent transfers of value from individuals dissuaded from smoking to the general public. Negative entries represent transfers in the opposite direction.

vi. *Summary of benefits accruing to dissuaded smokers.* Table 8 of this document presents benefits estimates that reflect a variety of net-to-gross ratios, ranging, as discussed in Technical Appendix X5, from the 7

[14] The difference between what a supplier is paid for a good or service and the marginal cost of supplying that good or service.

percent derived from the work of Gruber and Köszegi to the 90 percent suggested in a public comment. Also presented are the net internal benefits results derived from Warner *et al.*'s work on the value to smokers of cessation programs. For each discount rate and VSLY, we also report the midpoint between the lower and upper bound benefits estimates, where the upper bound is yielded by the 90 percent net-to-gross benefits ratio and the lower bound by the 7-percent ratio in some cases and by the cessation value approach in others. Given the great variation in estimates of net benefits to dissuaded smokers, we follow the recommendation of OMB Circular A–4 and use the midpoints for our primary calculations in the remainder of this analysis. The resulting midpoints range from $4.37 to $12.56 billion (with a 3-percent discount rate) or $1.02 to $2.86 billion (with a 7-percent discount rate). We emphasize that all the net benefits appearing in table 8 are intrapersonal and thus could not be positive if all tobacco consumers were time-consistent, fully rational, self-controlled, able to resist temptation, and in possession of perfect and complete information; instead, our results are qualitatively consistent with policy implications of economic models in which consumers are characterized by hyperbolic discounting, incorrect forecasting, temptation utility or self-control problems (in addition to Gruber and Köszegi (Ref. 104), *see* Bernheim and Rangel (Ref. 105) and Gul and Pesendorfer (Ref. 110)) and with Gruber and Mullainathan's (Ref. 182) examination of the effect of cigarette excise taxes on the happiness of individuals with a high propensity to smoke.

Table 8.--Present Value of Net Internal (i.e., Intrapersonal) Benefits ($ millions)

	VSLY=$106,308		VSLY=$212,615		VSLY=$318,923	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Totals Calculated with Alternative Methods or Net-to-Gross Benefits Ratios:						
90 Percent Ratio Derived from Public Comment	8,364.3	1,894.2	16,555.7	3,650.2	24,747.1	5,406.1
24 Percent Ratio Derived from Gruber (Ref. 133)	2,254.7	506.9	4,478.0	983.5	6,701.3	1,460.1
7 Percent Ratio Derived from Gruber and Köszegi (Ref. 104)	624.2	137.7	1,250.7	272.0	1,877.2	406.3
Value of Cessation Derived from Warner et al. (Ref. 131)	370.3	322.4	370.3	322.4	370.3	322.4
Midpoint Between Lower and Upper Bounds	4,367.3	1,016.0	8,463.0	1,961.1	12,558.7	2,864.2
Allocation of Midpoint Total:						
Life-Years	3,534.2	700.2	6,920.2	1,402.8	10,305.1	2,075.0
Health Status	742.8	241.6	1,454.5	484.0	2,165.9	715.9
Medical Expenditure Reduction	215.3	126.1	210.8	126.3	209.3	124.6
Other Financial Effects	-125.0	-51.9	-122.4	-52.0	-121.5	-51.3

3. Reduced Fire Costs

Each year, fires started by lighted tobacco products kill and injure people and destroy structures and other property. In the United States in 2007, civilian deaths caused by smoking-related fires totaled 720, with direct property damage of $530 million (Ref. 141). A reduction in the number of smokers, and the coinciding number of cigarettes smoked, will reduce the number of future fires.

FDA estimates the rule-induced decrease in cigarettes smoked by multiplying together the percentage change in smoking whose calculation was described in section XI.D.1 of this document, the projected population in a given year (Ref. 130) and age-appropriate discounted lifetime cigarette consumption (in packs) per smoker. FDA calculates average consumption for 18- to 23-year-olds using the May 2006, August 2006, and January 2007 Tobacco Use Supplements to the Current Population Survey (Ref. 142). Sloan *et al.* (Ref. 116) report lifetime discounted consumption for typical 24-year-old smokers. Comparing against total consumption in 2006 (the most recent year for which the FTC (Ref. 143) reports cigarette sales), we find that discounted lifetime cigarette consumption will decrease by an amount equivalent to 3.9 percent (using a 3-percent discount rate) or 2.1 percent (using a 7-percent discount rate) of a present-day annual total as a result of the final rule.

The rule-induced percentage reduction in fires may not equal the percentage reduction in cigarette consumption, however, because all 50 States have passed legislation that requires cigarettes to be self-extinguishing or fire-safe (Ref. 144). FDA acknowledges some uncertainty in the effectiveness rate of fire-safe cigarettes; [15] for this analysis, we

[15] One of the first States to enact these laws, New York, requires cigarettes to self-extinguish 75 percent of the time (Ref. 145). Data from New York show a reduction in smoking-caused fires of about 10.6 percent from the average of the 4 years (2000 to 2003) prior to passage of the fire-safe cigarette law to the first 2 years (2006 to 2007) after implementation was complete (Ref. 146).

estimate that 10.6 percent of apparently rule-induced future fire reductions would have been avoided even without this final rule due to fire-safe cigarette design.

The National Fire Protection Association (Ref. 147) reports the percentages of fire fatalities by age category; along with the CDC's estimate of average American life expectancy (Ref. 136), these data allow FDA to calculate that the average number of life-years lost by fire victims is approximately 37.3; we project that total discounted life-years saved as a result of the rule will be 317.4 (at a 7-percent discount rate) or 1,198.5 (at a 3-percent discount rate). Using—as in sections XI.D.2.b.ii and XI.D.2.b.iii of this document—VSLY ranging from $106,308 to $318,923, FDA estimates total rule-induced fire-cost savings of $106.0 to $262.5 million (at a 3-percent discount rate) or $34.1 to $76.5 million (at a 7-percent discount rate); of these totals, $12.9 (7-percent discount rate) or $27.7 million (3-percent discount rate) consists of averted property damage, with the remainder being the value of life-years saved. These estimated savings may significantly underestimate the final rule's fire-related benefits because they exclude noncivilian mortality and the value of reduction in fire-caused nonfatal injuries. There will, however, be some double counting between the estimated fire-related mortality benefits and the mortality benefits estimated in section XI.D.2.b.ii of this document to the extent that it is smokers themselves who are killed in cigarette-caused fires.

4. Summary of Benefits

The discussion above demonstrates the considerable magnitude of the economic benefits available from smoking reduction efforts. As shown in table 9a of this document, our midpoint benefits estimates range from $5.21 to $13.55 billion (with a 3-percent discount rate) or $1.38 to $3.27 billion (with a 7-percent discount rate). Estimates are presented as annualized values in table 9b of this document, reported over time in Appendix X3, and subjected to Uncertainty Analysis in Technical Appendix X6. Nonquantified benefits include reductions in nonsmoker morbidity and mortality associated with passive smoking and mothers smoking during pregnancy.

Table 9a.--Present Value of Benefits ($ mil)

	VSLY=$106,308		VSLY=$212,615		VSLY=$318,923	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Totals Calculated with Alternative Methods or Net-to-Gross Benefits Ratios:						
90 Percent Ratio Derived from Public Comment	8,470.3	1,928.3	16,740.0	3,705.5	25,009.7	5,482.6
24 Percent Ratio Derived from Gruber (Ref. 133)	2,360.7	541.0	4,662.3	1,038.8	6,963.8	1,536.6
7 Percent Ratio Derived from Gruber and Köszegi (Ref. 104)	730.2	171.8	1,435.0	327.3	2,139.7	482.8
Value of Cessation Derived from Warner et al. (Ref. 131)	476.3	356.5	554.6	377.7	632.8	398.9
Midpoint Between Lower and Upper Bounds	5,206.4	1,380.3	9,380.3	2,346.6	13,554.3	3,271.0
Allocation of Midpoint Total:						
Life-Years	3,534.2	700.2	6,920.2	1,402.8	10,305.1	2,075.0
Health Status	742.8	241.6	1,454.5	484.0	2,165.9	715.9
Medical Expenditure Reduction	416.2	241.2	411.7	241.4	410.1	239.6
Other Financial Effects	407.2	163.3	409.8	163.2	410.7	163.9
Fire Loss	106.0	34.1	184.3	55.3	262.5	76.5

Table 9b.--Annualized Value of Benefits ($ mil)

	VSLY=$106,308		VSLY=$212,615		VSLY=$318,923	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Totals Calculated with Alternative Methods or Net-to-Gross Benefits Ratios:						
90-Percent Ratio Derived from Public Comment	569.3	182.0	1,125.2	349.8	1,681.0	517.5
24-Percent Ratio Derived from Gruber (Ref. 133)	158.7	51.1	313.4	98.1	468.1	145.0
7-Percent Ratio Derived from Gruber and Köszegi (Ref. 104)	49.1	16.2	96.5	30.9	143.9	45.6
Value of Cessation Derived from Warner et al. (Ref. 131)	32.0	33.6	37.3	35.7	42.5	37.7
Midpoint Between Lower and Upper Bounds	349.9	130.3	630.5	221.5	911.1	308.8
Allocation of Midpoint Total:						
Life-Years	237.6	66.1	465.1	132.4	692.7	195.9
Health Status	49.9	22.8	97.8	45.7	145.6	67.6
Medical Expenditure Reduction	28.0	22.8	27.7	22.8	27.6	22.6
Other Financial Effects	27.4	15.4	27.5	15.4	27.6	15.5
Fire Loss	7.1	3.2	12.4	5.2	17.6	7.2

E. Costs

Implementation of this final rule, and the statutory requirements directly linked to it, will create new burdens for cigarette manufacturers. In particular, manufacturers will incur the upfront costs associated with a major labeling change.[16] There will be additional ongoing costs associated with equal and random display of the warnings required in this rule, as mandated by the Tobacco Control Act. Cigarette manufacturers and retailers will be responsible for the removal of noncompliant point-of-sale advertising. Consumers are likely to ultimately bear a share of these costs in the form of increased prices. In addition, the tobacco industry and possibly other sectors will experience lost sales and employment, but these revenue transfers will be offset by gains to other sectors, as discussed in the ''Distributional Effects'' section of this document.

1. Number of Affected Entities

Labeling and advertising requirements will affect domestic cigarette manufacturers and importers of foreign-made cigarettes. Statistics of U.S. Businesses data show that there were 24 cigarette manufacturing firms in the United States in 2007 (Ref. 148). An undetermined number of importers will also be affected.

Noncompliant point-of-sale advertising will be removed by manufacturers (or importers) and retailers. We use detailed data from the 2002 Economic Census report on product line sales for establishments with payroll to estimate the percentage of various types of retail establishments that sell tobacco products. Searching by the Economic Census product line 20150 (cigars, cigarettes, tobacco, & smokers' accessories), we find accommodation and food service establishments (NAICS 72) and retail trade establishments (NAICS 44–45) that report tobacco sales (Refs. 149 and 150). Although some establishments in other industries may have unreported sales of tobacco products, the product line sales data provide a reasonable basis to determine which establishments will be affected by the rule.

[16] All of the upfront costs of this rule are assumed to occur in the first period of the time horizon of this rule (2012). The cost tables present raw undiscounted calculations of these one-time costs. For summary tables requiring a present value, these costs are discounted 1 year back to the present (2011).

Table 10.--Establishments With Payroll That Sell Tobacco Products, 2002 Economic Census

Kind of Business	NAICS	Number in NAICS	Number Selling Tobacco Products	Percentage Selling Tobacco Products
General merchandise	452	40,723	6,991	17%
Food & beverage	445 excluding 44512	119,592	65,255	55%
Convenience[a]	44512	29,212	24,871	85%
Gasoline stations with convenience[a]	44711	93,691	86,152	92%
Gasoline stations	44719	27,755	8,745	32%
Health & personal care	446	81,797	17,761	22%
Other retail establishments	[a]	595,558	3,470	1%
Accommodation and food services	72 excluding 7224	516,734	12,347	2%
Drinking places	7224	48,856	11,490	24%
Tobacco stores	453991	6,184	6,184	100%
Nonstore retailers	454	49,000	848	2%
Vending machine operators	4542	5,921	892	15%
TOTAL		1,615,023	245,006	15%

Sources: Refs. 149 and 150

[a] Includes NAICS 441, 443, 444, 448, 451, 453 excluding 453991

Because the 2007 Census data on product line sales for retail establishments with employees are not yet available, we update the number of various types of retail establishments using 2007 Statistics of U.S. Businesses data but assume the share of establishments selling tobacco products is unchanged (since 2002) within each category. Likewise, we lack 2007 Census data on product line sales for nonemployer establishments. Without additional information, we assume that, within a NAICS category, the share of establishments selling tobacco products will be the same for nonemployer establishments in 2007 as for establishments with payroll in the 2002 Census. As shown in table 11 of this document, we estimate that about 249,000 retail establishments with payroll and 126,000 nonemployer establishments sell tobacco products.

Table 11.--Establishments That Sell Tobacco Products

Kind of Business	NAICS		Establishments With Payroll		Nonemployer Establishments	
		Percentage Selling Tobacco Products[a]	Number[b]	Estimated Number Selling Tobacco Products	Number[c]	Estimated Number Selling Tobacco Products
General merchandise stores	452	17%	47,456	8,147	32,978	5,661
Food & beverage stores	445 excluding 44512	55%	122,858	67,037	104,026	56,761
Convenience stores	44512	85%	28,173	23,986	e	
Gasoline stations with convenience stores	44711	92%	95,389	87,713	e	
Gasoline stations	44719	32%	20,144	6,347	9,454	2,979
Health & personal care stores	446	22%	89,406	19,413	138,800	30,138
Other retail stores	D	1%	600,537	3,499	735,266	4,284
Accommodation and food services	72 excluding 7224	2%	585,541	13,991	281,104	6,717
Drinking places	7224	24%	46,948	11,041	27,170	6,390
Tobacco stores	453991	100%	6,458	6,458	e	
Nonstore retailers	454 excluding 4542	2%	42,565	737	782,759	13,547
Vending machine operators	4542	15%	5,158	777	27,595	4,157
Total		15%	1,690,633	249,147	2,139,152	126,477

[a] Percentage of establishments with payroll from table 10 of this document.
[b] Ref. 148
[c] Ref. 151
[d] Includes NAICS 441, 443, 444, 448, 451, 453 excluding 453991
[e] Data on nonemployer establishments unavailable for this NAICS category

2. Costs of Changing Cigarette Labels

We have updated our analysis of the cost of changing cigarette labels based on the availability of improved estimates generated by the new FDA labeling cost model. Unless stated otherwise, our estimates in this analysis come from the new model.

The front and back of every cigarette package must be redesigned to incorporate graphic warnings that will occupy the entire top half, and the current warning will be eliminated. This is classified by the labeling model as a major change. (Any change that affects more than one color or changes the layout enough to require a redesign is major.) In addition, the requirement to incorporate nine different warnings will increase costs beyond what the labeling model estimates. FDA accounted for the additional warnings by first calculating the standard cost of a major change for cigarette labels and then inflating specific cost components expected to increase as a direct result of the requirement for nine warnings.

The FDA labeling cost model incorporates three potential cost components of a labeling change: Label design costs (incurred on a per-UPC basis), inventory costs (incurred on a per-unit basis), and testing costs (incurred on a per-formulation basis). Because the model has a greater focus on analytic testing (*e.g.,* measuring fat grams in a candy bar) than on market testing (which is the aspect of testing applicable to cigarettes), we perform several modifications to the model's testing cost estimation. First, we calculate costs on a per-brand, rather than per-formulation, basis and, second, we restrict the calculation of market testing costs to the largest firms. The large cigarette manufacturers can plausibly be expected to conduct quantitative studies and focus group testing for each of their brands to gauge the effect of the new graphic warnings and to study how they might best be able to mitigate their effects. By contrast, small manufacturers with lower sales revenues are highly unlikely to conduct expensive market testing in response to the new requirements. Further details of our estimation approach will be discussed in section XI.E.4 of this document.

The labeling model estimates that a total of 4,312 cigarette UPCs (3,789 branded and 523 private label) will be affected by this rule. However, it is estimated that label changes for 335 UPCs (8 percent of branded and 6 percent of private label) can be coordinated with previously scheduled, nonregulatory labeling changes. Coordination of a regulatory change with a nonregulatory change reduces the incremental burden of the regulatory change.

As discussed in the responses to comments, FDA follows its previous labeling cost model (Ref. 152) in assuming 10-percent rush charges under a 15-month compliance period. Using the labeling model cost estimates for uncoordinated changes and incorporating 10-percent rush charges, we estimate that labor costs for label design, including administrative labor costs as well as graphic design and prepress labor costs, are $4,147 to $10,890. Materials costs are estimated to be $6,644 to $10,934; included in this total are both prepress materials and printing plate costs.[17] Recordkeeping costs are estimated to be $55 to $99. Summing labor, materials, and recordkeeping costs yields a per-UPC label design cost of $10,846 to $21,923. The model estimates that for coordinated labeling changes, there is a per-UPC cost of $340 to $840. This cost is nonzero because there will still be

[17] Rotogravure, the most expensive printing method, is used for cigarette package labels.

some administrative labor and recordkeeping associated with coordinating a regulatory change with a previously scheduled, nonregulatory change. Total label design costs of this change are thus estimated to be $43 to $87 million.

Manufacturers incur costs if they discard unused label inventory at the end of the compliance period and thus have to print new labels instead of using that inventory. (There is also a small cost associated with disposal.) The labeling model estimates that 767,016 labels will be discarded at the end of the 15-month compliance period, each having a cost of $0.028 to $0.039. The inventory-replacement cost of this labeling change would then be $21,000 to $30,000. Table 12 of this document summarizes the total cost of a standard major labeling change (one warning per UPC), which is estimated to be $43 to $88 million.

Table 12.--Cost of a Standard Major Label Change for Cigarettes

	Low Cost	Medium Cost	High Cost
Label Design Costs			
Number of uncoordinated UPCs	3,978	3,978	3,978
Labor cost ($)	4,147	6,380	10,890
Materials cost ($)	6,644	6,996	10,934
Recordkeeping cost ($)	55	88	99
Per-UPC cost ($)	10,846	13,464	21,923
Label Design Costs for Uncoordinated UPCs ($)	43,145,388	53,559,792	87,209,694
Number of coordinated UPCs	335	335	335
Labor cost ($)	310	550	790
Materials cost ($)	0	0	0
Recordkeeping cost ($)	30	40	50
Per-UPC cost ($)	340	590	840
Label Design costs for Uncoordinated UPCs ($)	113,900	197,650	281,400
Total Label Design Costs ($)	43,259,288	53,757,442	87,491,094
Inventory Costs			
Number of discarded Labels	767,016	767,016	767,016
Unit cost per discarded label ($)	0.028	0.033	0.039
Total Inventory Costs ($)	21,093	25,312	29,530
Total Cost ($)	43,280,381	53,782,754	87,520,624

We expect materials costs for printing plates and prepress activities to be approximately nine times as large as previously calculated for uncoordinated UPCs because of the requirement for nine separate warnings. Each UPC will require nine printing plates, one for each warning label. Additionally, the incremental materials cost of a coordinated label change will be eight times the uncoordinated materials costs, because eight extra printing plates will be needed. We assume that this adjustment accounts for all the one-time costs that arise from the requirement to use nine warnings.[18] Table 13 of this document shows the total costs of the cigarette labeling change, making the adjustment for the nine-warning requirement. The labeling cost range increases to $273 million to $465 million.

[18] Some of the subcomponents of other cost categories might increase due to the nine-warning requirement, but there is far less reason to believe there will be a direct, proportional relationship between those cost categories and the number of warnings. For example, the part of the label that is under the manufacturer's control only has to be designed once because the same design will be paired with all nine labels. Likewise, the amount of unused inventory discarded is unaffected by the number of warnings used under the new requirements.

Table 13.--Cost of a Major Cigarette Label Change With Nine Warning Labels

	Low Cost	Medium Cost	High Cost
Label Design Costs[a]			
Number of uncoordinated UPCs	3,978	3,978	3,978
Labor cost ($)	4,147	6,380	10,890
Materials cost ($)	*59,796*	*62,964*	*98,406*
Recordkeeping cost ($)	55	88	99
Per-UPC cost ($)	63,998	69,432	109,395
Label Design Costs for Uncoordinated UPCs ($)	254,584,044	276,200,496	435,173,310
Number of coordinated UPCs	335	335	335
Labor cost ($)	310	550	790
Materials cost ($)	*53,152*	*55,968*	*87,472*
Recordkeeping cost ($)	30	40	50
Per-UPC cost ($)	53,492	56,558	88,312
Label Design costs for Uncoordinated UPCs ($)	17,919,820	18,946,930	29,584,520
Total Label Design Costs ($)	272,503,864	295,147,426	464,757,830
Inventory Costs			
Number of discarded Labels	767,016	767,016	767,016
Unit cost per discarded label ($)	0.0275	0.033	0.0385
Total Inventory Costs ($)	21,093	25,312	29,530
Total Cost ($)	272,524,957	295,172,738	464,787,360

[a] Undiscounted amount assumed to be incurred in the first period of the time horizon of this rule.

The cost of changing cigarette labels is largely driven by materials costs. The distribution for the estimate of materials costs is extremely skewed to the right, as evidenced by the fact that the low and medium estimate are much closer than the medium and high estimates. We report the 90th percentile range but note that the high value appears to be driven by a few extremely high values.

3. Ongoing Costs of Equal and Random Display

The Tobacco Control Act calls for equal and random display of the graphic warning images required by this rule. Although the initial design and implementation of a system for equal and random display will be part of the upfront label change, continued operation of such a system in subsequent years will have incremental ongoing administrative and recordkeeping costs. Such a system will be more burdensome than the current system of quarterly rotation of four warnings. FDA assumes that the ongoing yearly administrative labor cost per UPC will be equal to 10 percent of the (non-rush) administrative labor cost of an uncoordinated labeling change, and the yearly recordkeeping cost will be equal to 50 percent of the (non-rush) recordkeeping cost of an uncoordinated labeling change. As shown in table 14 of this document, FDA estimates that, under these assumptions, ongoing annual administrative and recordkeeping costs equal $375,000 to $876,000.

Table 14.--Estimated Ongoing Costs for Equal Random Display[a]

	Low Cost	Medium Cost	High Cost
Number of UPCs	4,313	4,313	4,313
Ongoing Admin. Costs per UPC	62	110	158
Total Ongoing Admin Costs	267,406	474,430	681,454
Ongoing RK Costs per UPC	25	40	45
Total Ongoing Recordkeeping Costs	107,825	172,520	194,085
Total Ongoing Costs	375,231	646,950	875,539

[a] Costs for maintaining a system of equal random display are assumed to be incurred in years 2 through 20 of the time horizon of this rule.

4. Market Testing Costs Associated With Changing Cigarette Package Labels

As stated previously, FDA expects that only the large manufacturers will conduct market tests for their brands. Using several State directories of certified tobacco products, FDA estimates that 75 brands are marketed by the 4 largest domestic manufacturers (Refs. 153 through 158). If we assume (as in the labeling model) that 8 percent of changes for these brands are coordinated, then changes for the remaining 69 brands are not coordinated. Including rush charges, the cost of focus group testing is estimated to range from $8,000 to $14,000 per brand, and the cost of a quantitative study is estimated to range from $14,000 to $105,000 per brand. Assuming both types of testing are conducted for 69 brands yields a total cost estimate ranging from $1.5 to $8.2 million with a medium estimate of $2.1 million, as shown in table 15 of this document. We assume that the requirement to use nine

different color graphic-text pairs does not affect these costs.

Table 15.--Cost of Market Testing[a]

	Low Cost	Medium Cost	High Cost
Number of brands to be tested	69	69	69
Cost of focus group testing ($)	8,030	11,000	13,970
Cost of quantitative studies ($)	13,750	19,800	105,160
Market testing cost per brand ($)	21,780	30,800	119,130
Total Market Testing Cost ($)	1,502,820	2,125,200	8,219,970

[a] Undiscounted amount assumed to be incurred in the first period of the time horizon of this rule.

5. Advertising Restrictions: Removal of Noncompliant Point-of-Sale Advertising

The principal effect of the restrictions on advertising in the rule stem from the requirement that retailers and manufacturers of cigarettes remove any point-of-sale advertising for cigarettes that fails to conform to the requirements. In this analysis, we estimate the social resource costs for the removal. In the analysis of FDA's 1996 final tobacco rule, we based much of our estimate of the cost of removing noncompliant point-of-sale advertising on a report from the Barents Group that used average removal costs for seven types of retail establishments, calculated using in-store surveys conducted by A.T. Kearney, Inc. (61 FR 44396 at 44580). We retain our assumptions from 1996 about the level of effort required to remove point-of-sale advertising. We acknowledge, however, that this approach may overstate or understate the costs for a particular action or type of business.

Table 16 of this document regroups the information from table 11 of this document according to the categories studied by A.T. Kearney. Because our analysis considers only the removal of point-of-sale advertising from physical retail locations, we do not include nonstore establishments. Table 17 of this document shows that, in current dollars, one-time per-establishment costs range from about $12 for ''other establishments'' to about $198 for convenience stores. To estimate the total costs to comply with the restriction on point-of-sale advertising, we apply the updated per-establishment costs from table 17 to affected establishments. As shown in table 18 of this document, the one-time costs to remove point-of-sale materials will total $45.4 million.

Table 16.--Estimated Number of Establishments Selling Cigarettes Products Affected by the Rule

Kind of Business	Establishments With Payroll[a]	Nonemployer Establishments[a]	Total
AT Kearney Category			
General Merchandise	8,147	5,661	13,808
Supermarket & Grocery	67,037	56,761	123,799
Convenience Stores	23,986		23,986
Convenience Stores with Gas	87,713		87,713
Service Stations	6,347	2,979	9,326
Drug Stores	19,413	30,138	49,552
Specialty Tobacco Stores	6,458		6,458
Other establishments [b]	28,531	17,391	45,922
Total	247,633	112,931	360,564

[a] Source: Table 11 of this document

[b] Includes miscellaneous retail establishments and accommodations and food services establishments (including drinking places), but excludes nonstore retailers.

Table 17.--Estimated Average Per-Establishment Costs to Remove Prohibited Materials[a]

AT Kearney Business Category	Remove Promotional Materials ($)	
	1996 dollars	Current dollars
General Merchandise	23.42	30.94
Supermarket & Grocery	125.14	165.30
Convenience Stores	150.02	198.16
Convenience Stores with Gas	146.43	193.42
Service Stations	36.09	47.67
Drug Stores	11.72	15.48
Specialty Tobacco Stores	123.21	162.75
Other establishments [b]	9.37	12.38

[a] Sources: 61 FR 44396 at 44585, Table 8; 1996 to 2009 (most recent) GDP deflator rose 32.1% (Ref. 132)
[b] Excludes adult-only establishments, nonstore retailers and vending machine operators.

Table 18.--Estimated One-Time Costs to Remove Point-of-Sale Materials from Affected Establishments

A.T. Kearney Category	Number of Establishments	Average Cost ($)	Total One-time Costs[b] ($ million)
General Merchandise	13,808	30.94	0.4
Supermarket & Grocery	123,799	165.30	20.5
Convenience Stores	23,986	198.16	4.8
Convenience Stores with Gas	87,713	193.42	17.0
Service Stations	9,326	47.67	0.4
Drug Stores	49,552	15.48	0.8
Specialty Tobacco Stores	6,458	162.75	1.1
Other establishments[a]	45,922	12.38	0.6
Total	360,564		45.4

Sources: Tables 16 and 17 of this document.
[a] Excludes adult-only establishments and nonstore retailers.
[b] Undiscounted costs assumed to be incurred in the first period of the time horizon of this rule.

6. Government Administration and Enforcement Costs

FDA's estimated internal costs for administering and enforcing this regulation are uncertain. As a best estimate, however, FDA projects that 25 full-time equivalent employees (FTEs) will be needed to implement the rule. Fully loaded employee costs vary with the type of employee (*e.g.,* field inspectors versus administrative), but an average of $247,049 per FTE places the dollar cost at approximately $6.2 million per year.

An additional cost of the final rule, borne by government but not necessarily FDA, arises due to the required reference to the cessation resource. The rule requires the final graphic warning labels to refer to an already-existing cessation resource. Therefore, only costs associated with additional traffic to that resource are attributable to this final rule. FDA has not quantified these costs.

7. Summary of Costs

Table 19 of this document summarizes the cost estimates from the preceding sections and table 20 of this document displays the present value and annualized value of costs. The tables in Technical Appendix X4 show the undiscounted stream of costs. The range of total costs presented in table 20 of this document is an approximate 90 percent confidence interval and, as such, corresponds to the uncertainty range of benefits presented in table 51 of this document. The distributions of costs and benefits, however, are not correlated; in other words, it may be the case that the actual effects of the rule fall in the high end of the cost range and the low end of the benefits range, or vice versa.

Table 19.--Summary of Costs

Requirements of the Rule	Annual ($ million)			One-Time ($ million)[a]		
	Low	Med	High	Low	Med	High
Private Sector						
Label Change				272.5	295.2	464.8
Market Testing				1.5	2.1	8.2
Point-of-Sale Advertising				45.4	45.4	45.4
Continuing Admin and Recordkeeping[b]	0.4	0.6	0.9			
Subtotal	0.4	0.6	0.9	319.5	342.7	518.4
Government						
FDA[c]	6.2	6.2	6.2			
Other (Cessation Resource)[c]						
Subtotal	6.2	6.2	6.2	-	-	-
TOTAL	6.6	6.8	7.1	319.5	342.7	518.4

[a] Undiscounted value of one-time costs assumed to be incurred in the first period of the time horizon of this rule.
[b] Ongoing cost assumed to be incurred in years 2 through 20.
[c] Annual costs assumed to be incurred in each period for a total of 20 years.

Table 20.--Present Value and Annualized Value of Costs

Requirements of the Rule	Present Value ($ million)						Annualized Costs ($ million)					
	3 percent			7 percent			3 percent			7 percent		
	Low	Med	High	Low	Med	High	Low	Med	High	Low	Med	High
Private Sector												
Label Change	264.6	286.6	451.2	254.7	275.9	434.4	17.8	19.3	30.3	24.0	26.0	41.0
Market Testing	1.5	2.1	8.0	1.4	2.0	7.7	0.1	0.1	0.5	0.1	0.2	0.7
Point-of-Sale Advertising	44.1	44.1	44.1	42.5	42.5	42.5	3.0	3.0	3.0	4.0	4.0	4.0
Continuing Admin and RK	5.2	9.0	12.2	3.6	6.2	8.5	0.4	0.6	0.8	0.3	0.6	0.8
Subtotal	315.4	341.8	515.5	302.2	326.6	493.0	21.2	23.0	34.7	28.5	30.8	46.5
Government												
FDA	91.9	91.9	91.9	65.4	65.4	65.4	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)												
Subtotal	91.9	91.9	91.9	65.4	65.4	65.4	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	407.3	433.6	607.4	367.6	392.0	558.4	27.4	29.1	40.8	34.7	37.0	52.7

F. Cost-Effectiveness Analysis

We measure the effectiveness of the final rule as the sum of saved life-years and QALYs. In order to assess the cost-effectiveness of the rule, we must adjust the costs to account for effects that are not captured by life-years or QALYs. As shown in detail in the previous section, we calculated the first 20 years' costs attributable to the rule and found present values of $367.6 to $558.4 million (using a 7-percent discount rate) or $407.3 to $607.4 million (using a 3-percent discount rate). We add to each total the estimated monetary value of lost consumer surplus (as discussed in detail in Technical Appendix X5, this was implicitly netted out of life-years and health improvement benefits estimates calculated in section XI.D.2.b of this document); this yields overall costs of $1.46 to $3.70 billion (using a 7-percent discount rate) or $5.33 to $15.55 billion (using a 3-percent discount rate). In order to focus on the costs associated with extensions of quality-adjusted life (*see* Ref. 103 at pp. 11–12), we then subtract both medical cost reductions and the value of property savings due to reductions in accidental fires and arrive at a net cost of $0.94 to $3.19 billion (using a 7-percent discount rate) or $4.38 to $14.59 billion (using a 3-percent discount rate).

Discounting over the same 20-year time period, we calculate that this rule will lead to 208,535 to 246,137 discounted smoking preventions or cessations. Similarly, we find that 18,534 to 86,326 discounted QALYs will be saved (this includes both fractional life-years associated with reduced morbidity and full life-years associated with reduced premature mortality—both for smokers themselves and for others caught in the path of cigarette-related fires). This yields a cost per smoking prevention of $4,530 to $59,287, and a cost per QALY saved of $50,746 to $172,082. Braithwaite *et al.* (Ref. 159) find that preferences in the United States are such that the threshold for cost-effective interventions is somewhere in the range of $109,000 to $297,000 per QALY saved.

Table 21.--Cost-Effectiveness

Cost ($)	3 percent			7 percent		
	Low	Medium	High	Low	Medium	High
Per Smoking Prevention	$17,798	$38,243	$59,287	$4,530	$9,470	$15,292
Per QALY Saved	$50,746	$109,040	$169,040	$50,972	$106,563	$172,082

G. Distributional Effects

This final rule will lead to losses to some segments of U.S. society that will most likely be offset by equal gains to some other segments of society; as such, these effects do not constitute net social costs or benefits and have not yet been discussed in detail in this Analysis of Impacts. In general, sectors affiliated with tobacco and tobacco products will lose sales revenues as a result of this final rule. Simultaneously, nontobacco-related industries will gain sales, because dollars not spent for tobacco products will be spent on other commodities.

1. Tobacco Manufacturers, Distributors, and Growers

FDA estimates that implementation of the regulation may reduce the annual cigarette consumption of U.S. smokers by 30.8 million packs (in 2013) to 40.5 million packs (in 2031). Meanwhile, the FTC (Ref. 143) reports that, in 2006, 17.5 billion cigarette packs were manufactured and distributed to consumers. These numbers imply that tobacco manufacturer revenues will be 0.176 percent lower in the rule's first year, and 0.231 percent lower in 2031, than they were in 2006. The U.S. Census Bureau (Ref. 160) reports that tobacco manufacturers' revenues totaled $41.6 billion in 2006; hence, the rule-induced decrease in annual tobacco sales will range from approximately $73.1 to $96.2 million. These estimates would rise somewhat higher if we were accounting for the decrease in price that accompanies the decrease in demand for a good (in this case, cigarettes). Experimental evidence from Mexico (Ref. 101) indicates that graphic warning labels may decrease smokers' willingness-to-pay for cigarettes by 17 percent; however, without supply elasticity data, we cannot determine how much this decline in willingness-to-pay will change cigarettes' market price.

We estimate that the tobacco manufacturing, warehousing, and wholesale trade sectors employ about 74,000 full-time workers (Ref. 148). Under the assumption of constant production-to-employment ratio, we project that a 0.176 to 0.231 percent reduction in sales will result in the displacement of 130 to 171 jobs among manufacturers, warehousers, and wholesalers.

Effects of the rule will also be observed in the agricultural sector. According to USDA's 2007 Census of Agriculture (Ref. 161), there are 16,234 tobacco farms. Upon implementation of the rule, these farms may shift some of their acreage from growing tobacco to producing other agricultural products.

2. National and Regional Employment Patterns

Several studies estimate the contribution of tobacco to the U.S. economy or, alternatively, the losses to the U.S. economy that will follow a decline in tobacco-related consumption. Economists have shown both theoretically and empirically that, for the nation as a whole, employment gains from spending on other products will offset any employment losses from reduced spending on tobacco products (Ref. 162). The major tobacco-growing states, however, will experience some adverse economic effects. An economic simulation of the regional impacts of spending on tobacco products carried out in 1994 found that after 8 years, a 2-percent per year fall in tobacco consumption (which substantially exceeds the FDA forecast for the effects of this final rule) would cause the loss of 36,600 jobs for the Southeast Tobacco region of the United States (0.2 percent of regional employment), whereas the nontobacco regions of the United States would gain 56,300 jobs (Ref. 122). That study, if carried out today, would find a much smaller net effect because total employment in tobacco-related industries has fallen. Overall, FDA finds that the income and employment effects associated with the estimated reduction in tobacco consumption will be small.

3. Retail Sector

As will tobacco growers, distributors, and manufacturers, tobacco retailers will be affected by any decrease in cigarette sales. Retailers will, however, be in a position to shift shelf space and promotional activities to nontobacco products, in order to take advantage of the increase in demand for other products that will be expected to accompany the decrease in spending on cigarettes. It is possible that some retailers who rely heavily on cigarette sales may not be able to fully offset their reduction in cigarette sales with sales of other products. Other retailers would then experience some of the gain in sales associated with an increase in demand for other products. This would be a distributional effect within the retail sector.

4. Advertising Industry

The overall impact of the rule on the advertising industry is uncertain. Advertiser revenue may decrease because advertisements with graphic warning labels are less desirable from a cigarette seller's standpoint and thus tobacco manufacturers will choose to conduct less advertising. On the other hand, advertising industry revenue may increase due to cigarette sellers' need to redesign advertisements to accommodate new warning labels and to devise new promotional strategies. In either case, few net social costs or benefits will be generated. Moreover, the effect on advertising revenue will likely be relatively small because spending on cigarette advertising has declined substantially in recent years and is now quite small compared with the 1980s and 1990s (Ref. 143). By 2006, expenditures on magazine advertising had fallen to about $50 million and outdoor advertising to under $1 million. Most of the remaining affected advertising expenditures were point-of-sale promotions, which totaled $240 million (Ref. 143).

5. Excise Tax Revenues

In 2009, Federal tobacco tax revenues totaled $16.3 billion, while State and local tobacco tax revenues totaled $16.5 billion (Ref. 163). This rule will decrease government tobacco tax revenues as fewer Americans consume cigarettes. Sales tax revenues generated through tobacco sales will also fall as a result of the rule, but those changes will be much smaller than the changes in excise tax collections and have not been quantified by FDA.

FDA estimates this change in excise tax revenues by multiplying together the percentage change in smoking rate, whose calculation was described in section XI.D.1 of this document; the projected population in a given year (Ref. 130); age-appropriate discounted lifetime cigarette consumption (in packs) per smoker; and current Federal and average State tax rates (Refs. 164 and 165). FDA calculates average consumption for 18- to 23-year-olds using the May 2006, August 2006, and January 2007 Tobacco Use Supplements to the Current Population Survey (Ref. 142). Sloan *et al.* (Ref. 116) report lifetime discounted consumption for typical 24-year-old smokers.

FDA estimates that average direct annual rule-induced decreases in excise tax collections will be approximately $33.4 million for State governments and $25.7 million for the Federal government. Approximately 25 percent of this reduction may be offset by increased sales of other taxable goods and services (Ref. 166); thus, the annual reductions in tax collections will be $25.1 million for State governments and $19.3 million for the Federal government. Assuming that excise taxes rise, on average, at the rate of inflation allows us to sum these values over the time horizon of our analysis, yielding an

overall revenue loss to State governments of $454.9 million (present value with a 7-percent discount rate) to $977.5 million (present value with a 3-percent discount rate) and to the Federal government of $348.1 million (present value with a 7-percent discount rate) to $749.8 million (present value with a 3-percent discount rate).

Because we cannot know if nominal cigarette excise taxes actually will increase at the rate of inflation, we also calculate these discounted present values for the case in which tax rates remain at their current nominal levels. In this case, the real tax rate will fall at the rate of inflation, which we forecast using the difference between interest rates for standard and inflation-protected long-term Treasury bills. The U.S. Department of the Treasury (Ref. 167) reports that, as of February 11, 2011, the composite rate for long-term standard bills was 4.33 percent, while the composite rate for long-term inflation-protected bills was 2.00 percent; the difference yields an inflation forecast of 2.33 percent per year. At this rate of inflation, the overall rule-induced tax revenue loss to State governments will be $327.8 to $590.0 million and to the Federal government will be $250.6 to $451.9 million. FDA emphasizes that these estimates would be altered, possibly a great deal, either by future changes in tax rates or inaccuracy in the inflation forecast.

We note that, leaving aside potential deadweight loss, there are two principal effects of tax reductions: Gains to former payers and losses to former recipients. Because these transfers exactly offset each other, there is no net social cost or benefit associated with the reduction in excise tax collections induced by the rule.

6. Government-Funded Medical Services, Insurance Premiums, and Social Security

Sloan *et al.* (Ref. 116) estimate that smokers use more medical services over their life cycles than do comparable nonsmokers; in 2000 dollars and discounted at a 3-percent rate, specific net costs are $3,757 per female 24-year-old smoker and $2,617 per male 24-year-old smoker. Smokers bear a portion of these net costs themselves, but a portion equaling $1,726 per female smoker or $1,245 per male smoker is borne by nonsmokers through increased private insurance premiums or taxes used to fund government health care programs; hence, a reduction in the U.S. smoking population will transfer value from smokers (who receive medical services paid partially by the general public) to nonsmokers. If nonsmokers' payment portions are adjusted for inflation and distributed over ages 24 to 100 as described in section XI.D.2.b.iv of this document (''Medical Services''), given FDA's projected 20-year reductions in smoking prevalence, this transfer totals $401.7 million. With a 7-percent discount rate, the total becomes $230.1 million. Sloan *et al.* indicate that this reduction will be distributed unequally across Medicare, Medicaid, and other insurance types. Details appear in table 22 of this document.

Table 22.--Distribution of Medical Cost Reductions ($ millions)

Discount Rate	Medicaid	Medicare Part A	Medicare Part B	Other Government	Private	Uninsured	Total
3%	104.2	-13.1	-174.1	50.4	359.1	75.2	401.7
7%	50.3	-14.5	-109.1	28.5	231.0	43.9	230.1

Note: Positive entries in the table represent transfers of value from individuals dissuaded from smoking to the general public. Negative entries represent transfers in the opposite direction.

Sloan *et al.* (Ref. 116, at p. 255) estimate the effect of smoking, per male and female smoker, on net Social Security, private pension, and life insurance outlays, as well as on income tax payments. In the cases of Social Security and private pension outlays, smoking-related premature mortality causes smokers to collect less from the programs than they contribute during their lifetimes. Therefore, any rule-induced reduction in the U.S. smoking population will shift value from members of the general public who pay Social Security taxes and who contribute to private pension plans to the individuals who are dissuaded from smoking by the regulation. A transfer in the opposite direction—from individuals dissuaded from smoking by the regulation to the general public—will occur in the realms of life insurance programs and income taxes.

Because Sloan *et al.* only report effects for 24-year-olds, we can only directly calculate these transfer effects for cohorts who are no older than 24 during the period from 2012 to 2031. The sum of these effects appears in the lower bound columns of table 23 of this document. For the upper bounds, we assume that effects are the same for smokers aged 25 and above as they are for 24-year-olds. In converting Sloan *et al.*'s present values, calculated with a 3-percent discount rate, to present values calculated with a 7-percent discount rate, further assumptions are necessary. We calculate the ratios of 7-percent present values to 3-percent present values for all gross benefits categories (life-years, health status, medical cost reductions, and fire loss reductions) and use the lowest and highest ratios for the lower and upper bounds in table 23. Finally, we note that we update Sloan *et al.*'s estimates using the most recent annual GDP deflator (Ref. 132).

Table 23.--Social Security, Income Taxes, Private Pensions, and Life Insurance Transfers ($ millions)

	Lower Bound Effect of Rule, Discounted at 3%	Midpoint Effect of Rule, Discounted at 3%	Upper Bound Effect of Rule, Discounted at 3%	Lower Bound Effect of Rule, Discounted at 7%	Midpoint Effect of Rule, Discounted at 7%	Upper Bound Effect of Rule, Discounted at 7%
Social Security Outlays	-280.4	-649.2	-1,017.9	-35.3	-263.2	-491.0
Income Taxes on Social Security-Taxable Earnings	327.0	746.5	1,166.1	41.1	301.5	561.8
Defined Benefit Private Pension Outlays	-397.4	-906.8	-1,416.2	-50.0	-366.1	-682.3
Life Insurance Outlays	582.7	1,341.7	2,100.6	73.3	543.1	1,102.8
Total	231.8	532.2	832.6	29.2	215.2	401.3

Note: Positive entries in the table represent transfers of value from individuals dissuaded from smoking to the general public. Negative entries represent transfers in the opposite direction.

H. International Effects

Of the $87.9 billion worth of tobacco products consumed in the United States in 2009 (Ref. 168), only $156 million consisted of imported cigarettes, with another $897 million imported as tobacco in a less-processed state (Refs. 169 and 170). As in the United States, foreign manufacturers, distributors, and growers of tobacco and tobacco products will lose revenue as a result of the rule, though their loss will be a small fraction of the overall revenue loss. As consumers who would have been smokers purchase other products, there could be a shift in patterns of international trade, depending on where the preferred substitute products are made.

The rule does not apply to cigarettes manufactured for export, whose value totaled $417 million in 2009 (Ref. 169).

I. Regulatory Alternatives

We compare the rule to two hypothetical alternatives: An otherwise identical rule with a 24-month compliance period and an otherwise identical rule with a 6-month compliance period. Even though we estimate costs and benefits for these alternatives, they do not provide viable regulatory options, as they are inconsistent with FDA's statutory mandate. We also describe alternatives associated with different graphical warnings.

1. 24-Month Compliance Period

Extension of the compliance period to 24 months reduces the one-time costs of this rule through three avenues: The number of UPCs that can be coordinated with a previously scheduled labeling change is increased, rush charges for the label design and market testing costs are eliminated, and discarded inventory costs are eliminated.

Table 24 of this document shows that extending the compliance period to 24 months would reduce the upfront label change cost by $30 to $53 million, to a total of $242 to $411 million. Table 25 of this document shows that market testing costs would be reduced by $0.3 to $1.8 million to a total of $1.2 to $6.4 million.[19] Extending the compliance period to 24 months would also delay all costs by about 9 months. We account for this by discounting the present value of costs an extra 9 months in the summary of alternatives table at the end of this section.

[19] The increase in the proportion of UPCs that can be coordinated is also expected to affect the number of brands that are market tested.

Table 24.--Cost of a Major Cigarette Label Change With Nine Warning Labels (24-Month)

	Low Cost	Medium Cost	High Cost
Label Design Costs[a]			
Number of uncoordinated UPCs	3,395	3,395	3,395
Labor cost ($)	3,770	5,800	9,900
Materials cost ($)	*54,360*	*57,240*	*89,460*
Recordkeeping cost ($)	50	80	90
Per-UPC cost ($)	58,180	63,120	99,450
Label Design Costs for Uncoordinated UPCs ($)	197,521,100	214,292,400	337,632,750
Number of coordinated UPCs	917	917	917
Labor cost ($)	310	550	790
Materials cost ($)	*48,320*	*50,880*	*79,520*
Recordkeeping cost ($)	30	40	50
Per-UPC cost ($)	48,660	51,470	80,360
Label Design costs for Uncoordinated UPCs ($)	44,621,220	47,197,990	73,690,120
Total Label Design Costs ($)	242,142,320	261,490,390	411,322,870
Total Cost ($)	242,142,320	261,490,390	411,322,870
Change from 15-month Compliance Period	-30,382,637	-33,682,348	-53,464,490

[a] Undiscounted amount assumed to be incurred in the first period of the time horizon of this rule.

Table 25.--Market Testing Cost With a 24-Month Compliance Period

Market Testing Cost[a]	Low Cost	Medium Cost	High Cost
Number of brands to be tested	59	59	59
Cost of focus group testing ($)	7,300	10,000	12,700
Cost of quantitative studies ($)	12,500	18,000	95,600
Market testing cost per brand ($)	19,800	28,000	108,300
Total Market Testing Cost ($)	1,168,200	1,652,000	6,389,700
Change from 15-month Compliance Period	-334,620	-473,200	-1,830,270

[a] Undiscounted value of costs assumed to be incurred in the first period of the time horizon of this rule.

Extending the compliance period to 24 months would delay the accrual of health and fire reduction benefits by 9 months. An approximation of the effect of this delay may be found by discounting, at 3- and 7-percent discount rates, the previously calculated total benefits. As shown in table 26 of this document, FDA finds that a 24-month compliance period would decrease the present value of benefits by between $65.4 and $294.6 million.

Table 26.--Present Value of Benefits with 24-Month Compliance Period ($ million)

	VSLY=$106,308		VSLY=$212,615		VSLY=$318,923	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Life-Years	3,456.7	665.6	6,768.4	1,333.4	10,079.1	1,972.4
Health Status	726.5	229.6	1,422.6	460.1	2,118.4	680.5
Medical Expenditure Reduction	407.0	229.2	402.6	229.4	401.1	227.8
Other Financial Effects	398.2	155.2	400.8	155.1	401.7	155.8
Fire Loss	103.7	32.4	180.2	52.6	256.8	72.7
TOTAL	5,092.2	1,312.0	9,174.7	2,230.5	13,257.1	3,109.2
Change from 15-Month Compliance Period	-114.2	-68.3	-205.7	-116.1	-297.2	-161.8

2. 6-Month Compliance Period

With a 6-month compliance period, the labeling cost model assumes that there is not enough time for any of the labeling changes to be coordinated with previously scheduled changes. Also, FDA accepts the labeling model's assumption of 40 percent rush charges, rather than assuming 10-percent rush charges as we did with a 15-month compliance period. The labeling model further assumes that 12 months is the shortest compliance period that can be met without resorting to covering up the old labels with stickers as a temporary solution. Therefore, with a 6-month compliance period, the cost of discarded inventory is the same as under a 12-month compliance period, but there is an additional cost for applying appropriate stickers to cover the old package label design.

The model, based on current sales data, estimates the number of units sold annually to be about 8 billion. Therefore, 4 billion units would be relabeled with stickers. The per-unit cost for the sticker and application is between $0.045 and $0.323. Reducing the compliance period to 6 months would then increase label change costs by $258 to $1,430 million to a total of $531 to $1,895 million. It would also increase the market testing costs by $0.6 to $3 million to a total of $2 to $11 million. Finally, shortening the compliance period to 6 months would move all costs up by about 9 months. We account for this by compounding the present value of costs 9 months in the summary of alternatives table at the end of this section.

Table 27.--Cost of a Major Cigarette Label Change With Nine Warning Labels (6-Month)

	Low Cost	Medium Cost	High Cost
Per-UPC Costs[a]			
Number of uncoordinated UPCs	4,312	4,312	4,312
Labor cost ($)	5,278	8,120	13,860
Materials cost ($)	*76,104*	*80,136*	*125,244*
Recordkeeping cost ($)	70	112	126
Per-UPC cost ($)	81,452	88,368	139,230
Per-UPC costs for Uncoordinated UPCs ($)	351,221,024	381,042,816	600,359,760
Total Per-UPC Costs ($)	351,221,024	381,042,816	600,359,760
Per-Unit Costs			
Number of discarded labels	1,087,966	1,087,966	1,087,966
Unit cost per discarded label ($)	0.035	0.042	0.049
Discarded Inventory Cost	38,079	45,695	53,310
Sticker and application costs per unit ($)	0.0448	0.115	0.3234
Number of units sold in 6 months	4,002,097,332	4,002,097,332	4,002,097,332
Sticker cost ($)	179,293,960	459,440,774	1,294,278,277
Total Per-Unit Costs	179,332,039	459,486,468	1,294,331,588
Total Cost ($)	530,553,063	840,529,284	1,894,691,348
Change from 15-month Compliance Period	258,028,106	545,356,547	1,429,903,987

[a] Undiscounted value of costs assumed to be incurred in the first period of the time horizon of this rule.

Table 28.--Market Testing Cost With a 6-Month Compliance Period

Market Testing Cost[a]	Low Cost	Medium Cost	High Cost
Number of brands to be tested	75	75	75
Cost of focus group testing ($)	10,220	14,000	17,780
Cost of quantitative studies ($)	17,500	25,200	133,840
Market testing cost per brand ($)	27,720	39,200	151,620
Total Market Testing Cost ($)	2,079,000	2,940,000	11,371,500
Change from 15-month Compliance Period	576,180	814,800	3,151,530

[a] Undiscounted value of costs assumed to be incurred in the first period of the time horizon of this rule.

Reducing the compliance period to 6 months would hasten the accrual of health and fire reduction benefits by 9 months. An approximation of the effect of this change in timing may be found by compounding, at 3- and 7-percent discount rates, the previously calculated total benefits. As shown in table 29 of this document, FDA finds that a 6-month compliance period would increase benefits by between $68.8 and $301.2 million.

Table 29.--Present Value of Benefits With 6-Month Compliance Period ($ million)

	VSLY=$106,308		VSLY=$212,615		VSLY=$318,923	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Life-Years	3,613.4	736.7	7,075.3	1,475.8	10,536.1	2,183.1
Health Status	759.5	254.2	1,487.1	509.2	2,214.5	753.2
Medical Expenditure Reduction	425.5	253.7	420.9	253.9	419.3	252.1
Other Financial Effects	416.3	171.8	419.0	171.7	419.9	172.5
Fire Loss	108.4	35.9	188.4	58.2	268.4	80.5
TOTAL	5,323.1	1,452.2	9,590.6	2,468.8	13,858.1	3,441.3
Change from 15-Month Compliance Period	116.7	71.9	210.3	122.2	303.8	170.3

3. Alternative Graphic Images

A legally available alternative to this rule would be to select a different set of graphic images. Although we are unable to quantify the effects of different graphic images, we note that some images may have a larger impact on smoking rates than other images.

Another alternative suggested would be to use more than nine graphic images to accompany the nine statutory warnings. We cannot assess the effect of additional images on the benefits of the rule but more images would increase costs. Although not all costs rise in proportion to the number of graphic images, the materials cost, which is the largest cost component, would rise in proportion to the number of images.

4. Summary of Regulatory Alternatives

Table 30 of this document summarizes the regulatory alternatives related to the compliance period by displaying ranges for the present values of the total benefits and total costs. Estimated ranges for the cost ratios (per smoking prevention and per life-year saved) of the rule and its regulatory alternatives appear in table 31 of this document.

Table 30.--Summary of Regulatory Alternatives

Compliance Period		Present Value of Total Benefits ($ million)[a]		Present Value of Total Costs($ million)[b]	
		3%	7%	3%	7%
24-Month	Total	5,092.2 to 13,257.1	1,312.0 to 3,109.2	369.2 to 541.6	322.1 to 481.7
(Final Rule) 15-Month	*Total*	*5,206.4 to 13,554.3*	*1,380.3 to 3,271.0*	*407.3 to 607.4*	*367.6 to 558.4*
6-Month	Total	5,323.1 to 13,858.1	1,452.2 to 3,441.3	673.1 to 2,043.5	641.0 to 1,996.5

[a] Range in benefits is based on a VSLY of $106,308 to $318,923.

[b] Range in costs is based on low cost and high cost values.

Table 31.--Incremental Cost-Effectiveness (CE) of Regulatory Alternatives

	Discount Rate = 3 percent				Discount Rate = 7 percent			
	Low	Incremental CE*	High	Incremental CE*	Low	Incremental CE*	High	Incremental CE*
24-Month Compliance:								
Per Smoking Prevention	$17,677	N/A	$59,068	N/A	$4,476	N/A	$15,413	N/A
Per QALY Saved	$50,401	N/A	$168,419	N/A	$50,369	N/A	$173,452	N/A
15-Month Compliance:								
Per Smoking Prevention	$17,798	$23,203	$59,287	$69,016	$4,530	$5,559	$15,292	$12,953
Per QALY Saved	$50,746	$66,157	$169,040	$196,782	$50,972	$62,557	$172,082	$145,766
6-Month Compliance:								
Per Smoking Prevention	$18,818	$64,322	$64,939	$317,100	$5,607	$26,299	$21,354	$137,819
Per QALY Saved	$53,655	$183,398	$185,157	$904,129	$63,094	$295,952	$240,304	$1,550,925

* As the compliance period decreases, the number of rule-induced smoking preventions and life-years saved increases. Hence, the incremental costs of 15-Month Compliance are calculated relative to 24-Month Compliance, and the incremental costs of 6-Month Compliance are calculated relative to 15-Month Compliance.

J. Impact on Small Entities

The Regulatory Flexibility Act requires agencies to prepare a final regulatory flexibility analysis if a final rule will have a significant effect on a substantial number of small entities. We expect this rule to have a significant effect on a substantial number of small entities. Consequently, this analysis, together with other relevant sections of this document, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

1. Description and Number of Affected Small Entities

The final rule will affect small entities in several industries, from tobacco farming to the retail industry. Most of the Nation's 16,234 tobacco farms are small; between 90.7 and 95.8 percent (between 14,732 and 15,555) of the farms growing tobacco in 2007 had total farm sales under the U.S. Small Business Administration (SBA) small business size standard of $750,000 (Refs. 161 and 171).

Table 32 of this document shows the breakdown of domestic cigarette manufacturers by employment size. Census data indicate that most cigarette manufacturing firms are small businesses, with only 4 of 24 firms employing more than 500 employees, while the small business size standard established by the SBA for this industry is 1,000 employees, so 20 small cigarette manufacturers will be affected (Refs. 148 and 171).

Table 32.--Cigarette Manufacturers by Number of Employees

Size by Number of Employees	Number of Firms
Less than 20	9
20 to 99	7
100 to 499	4

Source: Ref. 171
SBA size standard: 1,000 employees

Statistics of U.S. Businesses data show that 1,067 of 1,159 tobacco wholesale trade firms (92 percent) employ fewer than the 100-employee threshold that constitutes a small business according to the SBA (Refs. 148 and 171). If the size distribution of cigarette importers is similar to that of all tobacco wholesale trade firms, then 92 percent of them will be affected small businesses.

Also likely to be affected by the regulation are small retail and service entities that sell cigarettes. Retail establishments bear shared responsibility with manufacturers for the cost of removing noncompliant advertising. SBA size standards for the retail trade and the accommodations and food services industries differ from size categories used by the U.S. Census. Table 33 of this document shows the 2002 Census size categories that most closely match the SBA size standards. In all cases, the closest Census size category is smaller than the SBA size standard. As a consequence, any estimate based on the Census size categories may underestimate the number of affected small entities.

Table 33.--SBA Size Standards and Census Size Categories for Retail and Service Firms in NAICS Categories With Tobacco Product Line Sales[a]

NAICS with Tobacco Product Line Sales	Description of NAICS Category	SBA Size Standard ($ million)	Census Size Category ($ million)
General Merchandise			
452990	Other General Merchandise	11	10
452 excluding 452990	Department , Discount Department, Warehouse Clubs and Superstores	27	25
Supermarket and Grocery			
4452 and 4453	Other Food and Beverage Stores	7	5
445110	Supermarkets and Grocery	27	25
445120	Convenience Stores	27	25
447110	Convenience Stores with Gas	27	25
447190	Service Stations	9	5
446	Health and Personal Care Stores	7	5
453991	Specialty Tobacco Stores	7	5
[b]	Other Kinds of Business	Varies	Varies

Source: Refs. 171 through 173.
[a] Includes only firms with payroll.
[b] Includes NAICS 4413, 443112, 444, 448, 451, 4532, 453998, 72 (excluding 72231), 722310.

The Census reports establishment numbers for business by product line, and establishment and firm size by type of business, but provides no size data by type of business and product line. To estimate the number of affected entities that SBA classifies as small, we begin by counting the number of firms that fall below the Census size standard shown in table 33 of this document, including only firms in NAICS categories with tobacco product line sales. Next, we calculate the percentage of small firms in each NAICS category. Depending on the category of business, the percentage of small firms ranges from 41 percent for Discount Department, Warehouse Clubs and Superstores to almost 100 percent for Convenience Stores.

Table 34.--Estimated Percentage of Small Retail and Service Firms in NAICS Categories With Tobacco Product Line Sales[a]

NAICS	Description of NAICS Category	Number of Firms	Number of Firms Below Census Size Standard[b]	Percentage of Small Firms (%)
General Merchandise				
452110 452910	Discount Department, Warehouse Clubs and Superstores	88	36	40.9
452990	Other General Merchandise	7,451	7,320	98.2
General Merchandise Subtotal		7,539	7,356	97.6
Supermarket & Grocery				
445110	Supermarkets & Grocery	34,017	33,328	98.0
4452 and 4453	Other Food and Beverage Stores	34,807	34,082	97.9
Supermarket & Grocery Subtotal		68,824	67,410	97.9
445120	Convenience Stores	18,705	18,676	99.8
447110	Convenience Stores with Gas	37,437	36,848	98.4
447190	Service Stations	19,822	18,103	91.3
4461	Drug Stores	36,198	33,894	93.6
453991	Tobacco Stores	3,238	3,017	93.2
	Other Kinds of Business	589,400	572,619	97.2

Source: Refs. 172, 173, 149, and 150.

[a] Includes only firms with payroll.

[b] Based on the Census size standards shown in table 33 of this document.

Finally, we apply the percentages in table 34 of this document to our current estimate of the number of affected establishments with payroll (table 16 of this document). This approach implicitly assumes that small establishments are similar whether or not they sell tobacco products. In addition, we classify all nonemployer establishments as small. In total, we estimate that about 355,000 small retail and service establishments will be affected by the rule. This number represents about 98 percent of the estimated 361,000 establishments selling tobacco products.

Table 35.--Estimated Number of Small Establishments With Tobacco Product Line Sales by Kind of Business

Kind of Business	Percentage of Small[a] (%)	Number with Payroll[b]	Small with Payroll	Non-employers[b]	Estimated Total Number of Small Establishments
General Merchandise	97.6	8,147	7,949	5,661	13,611
Supermarket & Grocery	98.0	67,037	65,679	56,761	122,441
Convenience Stores	99.8	23,986	23,949	0	23,949
Convenience Stores with Gas	98.4	87,713	86,333	0	86,333
Service Stations	91.3	6,347	5,797	2,979	8,775
Drug Stores	93.6	19,413	18,178	30,138	48,316
Specialty Tobacco Stores	93.2	6,458	6,017	0	6,017
Other Establishments	97.2	28,531	27,719	17,391	45,110
Total		247,633	241,621	112,931	354,552

[a] From table 34 of this document.

[b] From table 16 of this document.

2. Description of the Potential Impacts of the Final Rule on Small Entities

a. *Effect on manufacturers.* In order to estimate how much of the label change and rotation costs will be incurred by small domestic cigarette manufacturers, FDA subtracts from the total costs those costs estimated to be incurred by large domestic manufacturers and foreign manufacturers. Scanner data from AC Nielsen indicate that approximately 49 percent of UPCs can be readily identified as belonging to a brand marketed by one of the four largest cigarette firms by volume (Refs. 153 through 158). Because the costs of label changes are roughly proportional to the number of UPCs, FDA then attributes 49 percent of the total label design and inventory costs to the four firms employing at least 500 people. FDA attributes an additional 3 percent of the label change costs to foreign manufacturers.[20] These adjustments leave 48 percent of costs, or $131 to $223 million in upfront costs and $180,000 to $420,000 in ongoing costs, to be incurred by the 20 small manufacturers. Assuming costs are distributed equally among these firms implies one-time costs of $6.5 to $11.2 million and ongoing costs of $9,000 to $21,000 per firm. Table 36 of this document compares these estimated compliance costs to average annual receipts in order to gauge the potential impact of labeling change requirements on small cigarette manufacturing firms. Because the number of UPCs is probably larger for larger firms, costs are likely greater for larger firms than for smaller firms; if so, this method overstates the impact on the smallest firms and understates the impact on the largest firms (within the category of firms employing fewer than 500 people).

Table 36.--Potential Impact of Compliance Costs on the 20 Small Cigarette Manufacturers

Size by Number of Employees	Number of Firms	Average Annual Receipts ($)	Average Compliance Costs ($)		Average Compliance Costs as a % of Average Annual Receipts	
			Lower Bound	Upper Bound	Lower Bound	Upper Bound
Panel 1: Upfront Label Change Costs						
Less than 20	9	11,195,000	6,541,000	11,155,000	58%	100%
20 to 99	7	21,265,000	6,541,000	11,155,000	31%	52%
100 to 499	4	147,896,000	6,541,000	11,155,000	4%	8%
Panel 2: Ongoing Rotation Costs						
Less than 20	9	11,195,000	9,000	21,000	0.1%	0.2%
20 to 99	7	21,265,000	9,000	21,000	0.0%	0.1%
100 to 499	4	147,896,000	9,000	21,000	0.0%	0.0%

Source: Statistics of U.S. Businesses, 2007 (Ref. 148)
SBA size standard: 1,000 employees

b. *Effect on retailers.* As shown in table 37 of this document, retail trade businesses account for almost all sales of tobacco products (Refs. 149 and 150). About 90 percent of tobacco product line sales occur at gasoline stations, food and beverage stores, general merchandise stores, or tobacco stores. Convenience stores (with gasoline stations and stand-alone convenience stores) account for about half of all tobacco product line sales.

[20] In 2008, 9.9 billion out of 345.3 billion individual cigarettes sold were imported (Ref. 123). FDA assumes the same proportion holds for UPCs. These UPCs should not overlap with those produced by the four largest domestic producers.

Table 37.--Sales of Tobacco Product Line by Kind of Business and Industry Sector[a]

Kind of Business and Industry Sector	Sales of Tobacco Product Line by Kind of Business		Sales of Tobacco Product Line by Industry Sector	
	($ billion)	(%)	($ billion)	(%)
Retail Trade				
NAICS 447-Gasoline Stations			22.2	43.3
Convenience Stores with Gas	21.2	41.3		
Gasoline Stations	1.0	2.0		
NAICS 445-Food and Beverage Stores			13.4	26.2
Supermarket & Grocery	7.7	15.0		
Convenience Stores	4.5	8.8		
Liquor Stores	1.2	2.4		
NAICS 452-General Merchandise			7.1	13.9
General Merchandise	7.1	13.9		
NAICS 453-Miscellaneous Store Retailers			5.8	11.3
Tobacco Stores	5.7	11.1		
Miscellaneous store retailers	0.1	0.3		
NAICS 446-Health and Personal Care Stores			1.5	3.0
Drug Stores	1.5	3.0		
NAICS 454-Nonstore Retailers			0.7	1.3
Nonstore Retailers	0.5	1.0		
Vending machine operators	0.2	0.4		
Other Subsectors [b]			0.1	0.2
Other Kinds of Business	0.1	0.2		
Accommodation & Food Services				
NAICS 72			0.4	0.8
Other establishments	0.3	0.5		
Drinking places	0.1	0.3		
Total			51.2	100

[a] Includes establishments with payroll with tobacco product line sales.
[b] Includes establishments in NAICS 441320, 443112, 444130, 444220, 448110, 448320, 451110, 451211, 451212, and 451220.

To illustrate the effects of the rule on a typical small retail store, we look at one-time costs for a convenience store and a convenience store with gasoline. We select these businesses because, as illustrated in table 37 of this document, sales of tobacco products in these stores account for about 50 percent of all tobacco sales. In addition, tobacco products are an important part of overall revenue for these stores, composing over 12 percent of total sales (as shown in table 38 of this document).

Table 38.--The Importance of Tobacco Sales by Kind of Business: Ranked by the Percentage of Total Sales From Tobacco Product Line

Kind of Business	Sales From Tobacco Product Line[a] ($ billion)	Total Sales From All Product Lines ($ billion)[b]	Percentage of Total Sales From Tobacco Product Line (%)
Tobacco Stores	5.7	6.5	86.9
Convenience Stores	4.5	18.1	25.0
Nonstore Retailers	0.5	2.4	20.3
Convenience Stores with Gas	21.2	173.4	12.2
Vending Machine Operators	0.2	1.7	11.2
Miscellaneous store retailers	0.1	1.2	11.2
Liquor Stores	1.2	12.8	9.7
Other Kinds of Business	0.1	1.4	6.5
Drinking places	0.1	3.9	3.5
Gasoline Stations	1.0	29.4	3.5
General Merchandise	7.1	246.1	2.9
Supermarket & Grocery	7.7	383.5	2.0
Drug Stores	1.5	80.0	1.9
Other Accommodation & Foodservice	0.3	33.3	0.8
Total	51.2	993.9	5.2

[a] Tobacco sales from table 37 of this document.

[b] Includes total sales for firms with tobacco product line sales (Refs. 149 and 150).

For both types of convenience stores, table 39 of this document shows that for the smallest firms with less than $250,000 in annual sales, the one-time costs of the rule will equal less than 2 percent of annual average sales of tobacco products. Furthermore, one-time costs total less than 0.1 percent of annual average sales of tobacco products for stores with $1 million or more in average annual sales. Although the impact on other small retail and service entities is uncertain, this example suggests that the rule will be unlikely to create a significant direct burden on small retail stores or service establishments.

If individual small retailers are unable to fully offset reduced cigarette sales with increased sales of other items, their sales revenue may fall. Although this decline would not be a social cost (as discussed in the distributional effects section) it would be a cost to the retailers who experience it. FDA has not quantified this additional potential effect, but believes that it is minor because the overall reduction in cigarette consumption is predicted to be less than one half of a percent, the demand for other goods is expected to increase, and retailers can be expected to shift shelf space to the other goods for which demand increases.

Table 39.--One-Time Costs as a Percentage of Average Sales of Tobacco Products for Convenience Stores and Convenience Stores With Gasoline

Sales Size of Firm	Number of Establishments	Sales	Sales of Tobacco Products	
			Average	One-time Costs as Percentage of Average
		($ million)	($ million)	(%)
Convenience Store-NAICS 445120[a]				
Less than $250,000	4,231	653	0.0	0.5
$250,000 to $499,999	5,296	1,920	0.1	0.2
$500,000 to $999,999	5,150	3,646	0.2	0.1
$1,000,000 to $2,499,999	3,586	4,915	0.3	0.1
$2,500,000 to $4,999,999	659	1,601	0.6	0.0
5,000,000 to 9,999,999	324	712	0.5	0.0
10,000,000 to 24,999,999	215	440	0.5	0.0
Convenience Stores with Gasoline- NAICS 447110[b]				
Less than $250,000	2,246	343	0.0	1.0
$250,000 to $499,999	3,801	1,425	0.0	0.4
$500,000 to $999,999	7,667	5,624	0.1	0.2
$1,000,000 to $2,499,999	14,309	22,303	0.2	0.1
$2,500,000 to $4,999,999	7,977	22,786	0.3	0.1

Source: Ref. 167.

[a] Tobacco product line sales account for 25.0 percent of sales for all firms in NAICS 445120 (see table 38 of this document); One-time costs equal $198.16 (see table 17 of this document).

[b] Tobacco product line sales account for 12.2 percent of sales for all firms in NAICS 447110 (see table 38); One-time costs equal $193.42 (see table 17).

3. Alternatives To Minimize the Burden on Small Entities

a. *Increase the compliance period to 24 months for small manufacturers or all manufacturers.* Allowing all manufacturers, or only small manufacturers, 24 months to comply with the label changes would eliminate overtime and rush charges, eliminate costs for replacing discarded inventory, and increase the number of UPCs for which the addition of graphic warning labels could be coordinated with previously scheduled label changes. Under a 24-month compliance period, the one-time label change costs would fall by an average of $0.7 to $1.3 million per small firm. Table 40 of this document compares the reduced estimated compliance costs to average annual receipts in order to gauge the potential impact of this regulatory alternative on cigarette manufacturing firms employing fewer than 500 people. As a comparison with table 36 of this document shows, this option would provide some relief, but the burden would remain significant. It would also delay the public health benefits of the rule and be inconsistent with FDA's statutory mandate.

Table 40.--Potential Impact of Compliance Costs on the 20 Small Cigarette Manufacturers With a 24-Month Compliance Period

Size by Number of Employees	Number of Firms	Average Annual Receipts ($)	Average Compliance Costs ($)		Average Compliance Costs as a % of Average Annual Receipts	
			Lower Bound	Upper Bound	Lower Bound	Upper Bound
Panel 1: Upfront Label Change Costs						
Less than 20	9	11,195,000	5,811,000	9,872,000	52%	88%
20 to 99	7	21,265,000	5,811,000	9,872,000	27%	46%
100 to 499	4	147,896,000	5,811,000	9,872,000	4%	7%
Panel 2: Ongoing Rotation Costs						
Less than 20	9	11,195,000	9,000	21,000	0.1%	0.2%
20 to 99	7	21,265,000	9,000	21,000	0.0%	0.1%
100 to 499	4	147,896,000	9,000	21,000	0.0%	0.0%

Source: Statistics of U.S. Businesses, 2007 (Ref. 148)
SBA size standard: 1,000 employees

b. *Allow small manufacturers to use one warning per UPC.* Allowing small cigarette manufacturers to use only one randomly selected warning and graphic image per UPC would reduce their upfront label change cost substantially. The costs to small businesses of implementing this option can be approximated by assuming that the 20

smallest firms bear 48 percent of the cost of a standard (one warning) cigarette label change. The average cost per small manufacturer would be reduced by $5.5 to $9 million per firm. Additionally, there would be some small cost at the beginning to ensure random selection of the warnings, but the ongoing annual rotation cost of $9,000 to $21,000 per firm would be eliminated. Table 41 of this document compares the reduced estimated compliance costs to average annual receipts in order to gauge the potential impact of this regulatory alternative on cigarette manufacturing firms employing fewer than 500 people. As a comparison with table 36 of this document shows, this alternative would provide significant relief. However, it is inconsistent with FDA's statutory mandate. Smokers who use only one specific product would not be exposed to all the warnings, which would likely hinder the effectiveness of this rule.

Table 41.--Potential Impact of Compliance Costs on the 20 Small Cigarette Manufacturers With One Label per UPC

Size by Number of Employees	Number of Firms	Average Annual Receipts ($)	Average Compliance Costs ($)		Average Compliance Costs as a Percentage of Average Annual Receipts	
			Lower Bound	Upper Bound	Lower Bound	Upper Bound
Panel 1: Upfront Label Change Costs						
Less than 20	9	11,195,000	1,039,000	2,100,000	9%	19%
20 to 99	7	21,265,000	1,039,000	2,100,000	5%	10%
100 to 499	4	147,896,000	1,039,000	2,100,000	1%	1%

Source: Statistics of U.S. Businesses, 2007 (Ref. 148)
SBA size standard: 1,000 employees

c. *Exempt small manufacturers from the labeling change requirements.* Exempting small manufacturers from the label change requirements would eliminate their label change costs and ongoing rotation costs (an average reduction of $6.5 to $11.2 million in upfront costs and $9,000 to $21,000 in ongoing costs), thus providing maximum relief. The combined market share of the four largest manufacturers was 89.7 percent in 2008 (Ref. 123). The immediate impact of exempting small manufacturers would therefore be to allow 10.3 percent of cigarettes to be marketed without graphic warning labels. This proportion would grow over time, however, as some consumers would be expected to switch to brands marketed without graphic warnings. This approach would be inconsistent with both FDA's statutory mandate and the public health objectives of this rule.

d. *Exempt small cigarette retailers from the point-of-sale advertising requirements.* Exempting small cigarette retailers from the point-of-sale advertising requirements would eliminate their need to remove noncompliant advertising, reducing their direct costs to zero. However, table 35 of this document shows that the overwhelming majority of retail establishments selling cigarettes are small. Although the few establishments operated by large firms might be expected to have higher volume, a significant proportion of consumers would continue to be exposed to advertising lacking the new graphic warnings. This situation would be inconsistent with the public health objective of the rule as well as FDA's statutory mandate.

XII. Paperwork Reduction Act of 1995

The required warning disclosures are the "public disclosure of information originally supplied by the Federal government to the recipient for th[at] purpose," and are, therefore, not within the scope of the Paperwork Reduction Act (*see* 5 CFR 1320.3(c)(2)).

XIII. References

The following references have been placed on display in the Division of Dockets Management (*see* **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday. (FDA has verified Web site addresses, 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 in 21 CFR Part 1141

Advertising, Incorporation by reference, Labeling, Packaging and containers, Tobacco, and Smoking.

Therefore, under the Federal Cigarette Labeling and Advertising Act, the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, chapter I of title 21 of the Code of Federal Regulations is amended by adding part 1141 to subchapter K to read as follows:

PART 1141—CIGARETTE PACKAGE AND ADVERTISING WARNINGS

Subpart A—General Provisions

Sec.
1141.1 Scope.
1141.3 Definitions.

Subpart B—Cigarette Package and Advertising Warnings

1141.10 Required warnings.
1141.12 Incorporation by reference of required warnings.
1141.14 Misbranding of cigarettes.

Subpart C—Additional Disclosure Requirements for Cigarette Packages and Advertising

1141.16 Disclosures regarding cessation.

Authority: 15 U.S.C. 1333; 21 U.S.C. 371, 387c, 387f; Secs. 201 and 202, Pub. L. 111–31, 123 Stat. 1776.

Subpart A—General Provisions

§ 1141.1 Scope.

(a) This part sets forth the requirements for the display of health warnings on cigarette packages and in advertisements for cigarettes. FDA may require additional statements to be displayed on packages and in advertisements under the Federal Food, Drug, and Cosmetic Act or other authorities.

(b) The requirements of this part do not apply to manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution within the United States.

(c) A cigarette retailer shall not be considered in violation of this part as it applies to the display of health warnings on a cigarette package if the package:

(1) Contains a health warning;

(2) Is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and

(3) Is not altered by the retailer in a way that is material to the requirements of section 4(a) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(a)) or this part, including by obscuring the warning, by reducing its size, by severing it in whole or in part, or by otherwise changing it in a material way.

(d) A cigarette retailer shall not be considered in violation of this part as it applies to the display of health warnings in an advertisement for cigarettes if the advertisement is not created by or on behalf of the retailer and the retailer is not otherwise responsible for the inclusion of the required warnings. This paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a health warning or that contains a warning that has been altered by the retailer in a way that is material to the requirements of section 4(b) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(b)), this part, or section 4(c) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(c)), including by obscuring the warning, by reducing its size, by severing it in whole or in part, or by otherwise changing it in a material way.

§ 1141.3 Definitions.

For the purposes of this part,

Cigarette means:

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; and

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1) of this definition.

Commerce means:

(1) Commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof;

(2) Commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or

(3) Commerce wholly within the District of Columbia, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, or Johnston Island.

Distributor means any person who furthers the distribution of cigarettes at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

Front panel and *rear panel* mean the two largest sides or surfaces of the package.

Importer means any person who imports any cigarette that is intended for sale or distribution to consumers in the United States.

Manufacturer means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette product.

Package means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

Person means an individual, partnership, corporation, or any other business or legal entity.

Required warning means the combination of one of the textual warning statements and its accompanying color graphic, which are set forth in ''Cigarette Required Warnings,'' which is incorporated by reference at § 1141.12.

Retailer means any person who sells cigarettes to individuals for personal consumption, or who operates a facility where vending machines or self-service displays of cigarettes are permitted.

United States, when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island. The term ''State'' includes any political division of any State.

Subpart B—Cigarette Package and Advertising Warnings

§ 1141.10 Required warnings.

(a) *Packages*—(1) It shall be unlawful for any person to manufacture, package,

sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part, one of the required warnings on the front and the rear panels.

(2) The required warning shall be obtained from the electronic images contained in ''Cigarette Required Warnings,'' which is incorporated by reference at § 1141.12, and accurately reproduced as specified in ''Cigarette Required Warnings.''

(3) The required warning shall appear directly on the package and shall be clearly visible underneath the cellophane or other clear wrapping.

(4) The required warning shall be located in the upper portion of the front and rear panels of the package and shall comprise at least the top 50 percent of these panels; *Provided, however,* that on cigarette cartons, the required warning shall be located on the left side of the front and rear panels of the carton and shall comprise at least the left 50 percent of these panels.

(5) The required warning shall be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation.

(b) *Advertisements*—(1) It shall be unlawful for any manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part, one of the required warnings.

(2) The text in each required warning shall be in the English language, except that:

(i) In the case of an advertisement that appears in a non-English publication, the text in the required warning shall appear in the predominant language of the publication whether or not the advertisement is in English; and

(ii) In the case of an advertisement that appears in an English language publication but that is not in English, the text in the required warning shall appear in the same language as that principally used in the advertisement.

(3) For English-language and Spanish-language warnings, each required warning shall be obtained from the electronic images contained in ''Cigarette Required Warnings,'' which is incorporated by reference at § 1141.12, and accurately reproduced as specified in ''Cigarette Required Warnings.''

(4) For foreign-language warnings, except for Spanish-language warnings, each required warning shall be obtained from the electronic images contained in ''Cigarette Required Warnings,'' which is incorporated by reference at § 1141.12, and accurately reproduced as specified in ''Cigarette Required Warnings,'' including the insertion of a true and accurate translation of the textual warning. The inserted textual warning must comply with the requirements of section 4(b)(2) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(b)(2)).

(5) The required warning shall occupy at least 20 percent of the area of each advertisement, and shall be placed in accordance with the requirements in the Federal Cigarette Labeling and Advertising Act.

(c) *Irremovable or permanent warnings.* The required warnings shall be indelibly printed on or permanently affixed to the package or advertisement. Such warnings, for example, must not be printed or placed on a label affixed to a clear outer wrapper that is likely to be removed to access the product within the package.

§ 1141.12 Incorporation by reference of required warnings.

''Cigarette Required Warnings'' Edition 1.0 (June 2011), consisting of electronic files, U.S. Food and Drug Administration, referred to at § 1141.3, § 1141.10(a) and (b), and § 1141.16(a), is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, FDA must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Also, you may obtain a copy of the material by contacting the Center for Tobacco Products, Food and Drug Administration, Office of Health Communication and Education, ATTN: Cigarette Warning File Requests, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–CTP–1373, or *cigarettewarningfiles@fda.hhs.gov.* You may also obtain the material at *http://www.fda.gov/cigarettewarningfiles.*

§ 1141.14 Misbranding of cigarettes.

(a) A cigarette shall be deemed to be misbranded under section 903(a)(1) of the Federal Food, Drug, and Cosmetic Act if its package does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part. A cigarette shall be deemed to be misbranded under section 903(a)(7)(A) of the Federal Food, Drug, and Cosmetic Act if its advertising does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part.

(b) A cigarette advertisement or package will be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act if it bears one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part. A cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act unless the manufacturer, packer, or distributor includes in all advertisements and packages issued or caused to be issued by the manufacturer, packer, or distributor with respect to the cigarette one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part.

Subpart C—Additional Disclosure Requirements for Cigarette Packages and Advertising

§ 1141.16 Disclosures regarding cessation.

(a) The required warning shall include a reference to a smoking cessation assistance resource in accordance with, and as specified in, ''Cigarette Required Warnings'' (incorporated by reference at § 1141.12).

(b) In meeting the smoking cessation needs of an individual caller, the smoking cessation assistance resource required to be referenced by paragraph (a) of this section must, as appropriate:

(1) Provide factual information about the harms to health associated with cigarette smoking and the health benefits of quitting smoking;

(2) Provide factual information about what smokers can expect when trying to quit;

(3) Provide practical advice (problem solving/skills training) about how to deal with common issues faced by smokers trying to quit;

(4) Provide evidence-based advice about how to formulate a plan to quit smoking;

(5) Provide evidence-based information about effective relapse prevention strategies;

(6) Provide factual information on smoking cessation treatments, including FDA-approved cessation medications; and

(7) Provide information, advice, and support that is evidence-based, unbiased (including with respect to products, services, persons, and other entities), and relevant to tobacco cessation.

(c) The smoking cessation resource must:

(1) Other than as described in this section, not advertise or promote any particular product or service;

(2) Except to meet the particularized needs of an individual caller as determined in the context of individual counseling, not selectively present information about a subset of FDA-approved cessation products or product categories while failing to mention other FDA-approved cessation products or product categories;

(3) Not provide or otherwise encourage the use of any drug or other medical product that FDA has not approved for tobacco cessation;

(4) Not encourage the use of any non-evidence-based smoking cessation practices;

(5) Ensure that staff providing smoking cessation information, advice, and support are trained specifically to help smokers quit by delivering unbiased and evidence-based information, advice, and support; and

(6) Maintain appropriate controls to ensure the criteria described in paragraphs (b) and (c) of this section are met.

(d) If the Secretary of the Department of Health and Human Services (Secretary) determines that a part of the smoking cessation assistance resource referenced by paragraph (a) of this section does not meet the criteria described in paragraphs (b) and (c) of this section, the Secretary shall take appropriate steps to address the noncompliance.

Dated: June 9, 2011.

Margaret A. Hamburg,

Commissioner of Food and Drugs.

Dated: June 9, 2011.

Kathleen Sebelius,

Secretary of Health and Human Services.

Note: The following Appendices will not appear in the Code of Federal Regulations.

Appendices

I. Technical Appendix X1: Smoking Rates
II. Technical Appendix X2: Life-Years
III. Technical Appendix X3: Timing of Benefits
IV. Technical Appendix X4: Timing of Costs
V. Technical Appendix X5: Additional Diagrams on Benefits
VI. Technical Appendix X6: Uncertainty Analysis
A. Alternative Estimation of Smoking Rate Reduction
B. Monte Carlo Simulation

I. Technical Appendix X1: Smoking Rates

FDA's primary and secondary methods for estimating the reduction in smoking rates realized in Canada due to that country's introduction, in December 2000, of graphic warning labels both involve several steps. In both methods, the first step is to estimate the smoking rate trend for Canada in the years from 1991 up to and including 2000. (We perform a similar analysis for the United States, but this will be used only in the primary method.)

In response to comments on the Preliminary Regulatory Impact Analysis of the proposed rule, we refine our estimate of the Canadian smoking rate trend by accounting for tax changes at the Federal and provincial levels. The Ontario Flue-Cured Tobacco Growers' Marketing Board (Ref. 174) reports time series of cigarette taxes for Canadian provinces and territories. (Because these time series only extend back to 1991, we have had to estimate a shorter time trend than the one used in the analysis of the proposed rule.) We find average tax levels for all of Canada by weighting by provincial and territorial populations (using Ref. 175). We then adjust nominal cigarette taxes for general inflation using the broad Canadian CPI (Ref. 176). (Canada has estimated a GDP deflator only since 2002, so we use the Canadian CPI, even though consumer price indices tend to be characterized by slight upward biases in their estimates of inflation.) Our results, along with results from an analogous estimation for the United States, are reported in Table 42.

Table 42.--Smoking Rate Trends, Canada and United States[a]

	Regression Results, Canada[b]	Regression Results, United States[d]
Intercept	Intercept = 4.455	Intercept = 3.451
	Standard Error = 0.215[c]	Standard Error = 0.202[c]
	t-statistic = 20.715[c]	t-statistic = 17.084[c]
Time Trend = *ln(Year - 1985)*	Coefficient = -0.377	Coefficient = -0.115
	Standard Error = 0.063[c]	Standard Error = 0.074[c]
	t-statistic = -6.012[c]	t-statistic = -1.551[c]
Excise Tax (*ln*)	Coefficient = -0.215	Coefficient = -0.101
	Standard Error = 0.080[c]	Standard Error = 0.106[c]
	t-statistic = -2.688[c]	t-statistic = -0.950[c]
N	7	5

[a] Underlying smoking rate data appear in table 4 of this document.

[b] Regression equation: *ln(SmokingRate) = Intercept + Coefficient*ln(Year-1985) + Coefficient*ln(ExciseTax) + error.*

[c] Standard errors and t-statistics reported here are not adjusted for uncertainty introduced by the use of survey data.

[d] Regression equation: *ln(SmokingRate) = Intercept + Coefficient* ln(Year-1985) + Coefficient*ln(ExciseTax) + error.*

Using the estimated time trend, we forecast the Canadian smoking rate that would have been realized post-2000 had graphic warning labels not been introduced in that country. The difference between the smoking rate forecast and the actual Canadian smoking rate yields the portion of the smoking rate that is unexplained apart from the introduction of graphic warning labels. Calculating the difference in the average unexplained smoking rate between 1994–2000 and 2001–09 yields the estimate of the effect of graphic warning labels, 0.574 percentage points, that appears in part (a) of Technical Appendix X6.

Table 43.--Impact of Graphic Warning Labels on Canadian Smoking Rate

	Smoking Rate, Canada[a]	Time Trend Forecast Smoking Rate, Canada	Unexplained Smoking Rate, Canada[b]
1994-95	30.5	30.391	0.109
1996-97	28.6	28.172	0.428
1998-99	27.7	26.237	1.463
1999	25.2	25.855	-0.655
2000	24.4	25.099	-0.699
2001	21.7	24.088	-2.388
2002	21.4	22.247	-0.847
2003	20.9	20.274	0.626
2004	19.6	19.596	0.004
2005	18.7	19.242	-0.542
2006	18.6	18.950	-0.350
2007	19.2	18.607	0.593
2008	17.9	18.291	-0.391
2009	17.25	17.957	-0.707

[a] Source: Health Canada (Refs. 126 and 127).
[b] Mean for 1994-2000 is 0.129; mean for 2001-09 is -0.445; difference in means is 0.574.

In our preferred estimation method (see section XI.D.1, above), we use the U.S. experience as an additional control. We find the unexplained smoking rate in the United States using calculations analogous to those used for Canada and tax data from the Centers for Disease Control and Prevention (Ref. 177) and Jamison *et al.* (Ref. 178), population data from the U.S. Census Bureau (Refs. 179 and 180), and inflation data from the U.S. Bureau of Economic Analysis (Ref. 132). We then calculate the difference in unexplained smoking rates between the United States and Canada. Finally, we again subtract the average for 1994–2000 from the average for 2001–09; this produces the estimate that graphic warning labels decrease the national smoking rate by 0.088 percentage points. Details appear in Table 44.

Table 44.--Impact of Graphic Warning Labels on Difference Between Unexplained United States and Canadian Smoking Rates

	Smoking Rate, United States[a]	Standard Error, Smoking Rate, United States[a]	Time Trend Forecast Smoking Rate, United States	Unexplained Smoking Rate, United States	Difference in Unexplained Smoking Rates (United States-Canada)[c]
1994-95	24.6	[b]	24.742	-0.142	-0.251
1996-97	24.558	0.29	24.213	0.344	-0.083
1998	23.918	0.30	23.971	-0.053	-1.516
1999	23.302	0.32	23.564	-0.261	0.393
2000	23.065	0.32	23.005	0.060	0.759
2001	22.644	0.30	22.869	-0.226	2.162
2002	22.262	0.32	22.141	0.121	0.967
2003	21.310	0.30	21.945	-0.635	-1.261
2005	20.724	0.31	21.538	-0.814	-0.272
2006	20.564	0.35	21.447	-0.882	-0.533
2007	19.449	0.40	21.211	-1.762	-2.356
2008	20.409	0.38	20.948	-0.539	-0.148
2009	20.513	0.37	20.190	0.323	1.030

[a] Sources: National Center for Health Statistics (Ref. 129) and FDA analysis of National Health Interview Survey (Ref. 128).
[b] Not reported for 1994, but likely to be near the standard error of 0.3 found for years 2000-03.
[c] Mean for 1994-2000 is -0.140; mean for 2001-09 is -0.051; difference in means is 0.088.

II. Technical Appendix X2: Life-Years

In calculating expected life-years saved per dissuaded smoker, FDA relies heavily on the life tables developed by Sloan *et al.* (Ref. 116). The life tables are calculated from the perspective of 24-year-olds, so the calculation of rule-induced effects on males and females who turn 24 sometime after the rule takes effect is relatively straightforward. In the following example, we will show the calculation of expected rule-induced effects for 24-year-old females, under the assumption of a 3 percent discount rate; the calculations for males or for a 7 percent discount rate would be analogous.

The life tables show that, of one hundred thousand females who smoke at their 24th birthdays, 99,939 will survive to their 25th birthdays and 99,876 to their 26th birthdays. Of one hundred thousand 24-year-old female nonsmoking smokers, 99,946 will survive to their 25th birthdays and 99,889 to their 26th birthdays. These numbers imply that, for every one hundred thousand females who smoke at their 24th birthdays, smoking will cause seven deaths between birthdays 24 and 25 and six deaths between birthdays 25 and 26. The tables continue to show number of survivors in each category (and thus the smoking-related excess probability of dying) for every birthday up to age 100; the discontinuation of the tables at this point requires us to assume no survival in either category to the one-hundred-and-first birthday.

Someone who dies at the age of 24 loses all the life-years up to and including age 100. Without discounting, this would be a total of 77 years; with a 3 percent discount rate, however, the total is 29.9 years. Similarly, someone who dies at age 25 loses 76 undiscounted or 29.8 discounted life-years. By multiplying together the age-specific discounted life-year loss and the age-specific smoking-related excess probability of dying, then summing over all ages, we arrive at the overall expected number of life-years saved per dissuaded female smoker. Using a discount rate of 3 percent, this result is (7/100,000)*29.9 + (6/100,000)*29.8 + … = 0.524.

For individuals who are older than 24 at the time of the rule's implementation, we want to perform a similar calculation; however, direct application of the nonsmoking smoker life tables is inappropriate because the life expectancy effect of smoking cessation at a particular age is almost certainly different than the effect of having refrained from smoking since at least the age of 24. Thus, it is necessary to develop age-specific survival probabilities for former smokers.

There are four possible events that a 24-year-old smoker can experience between any two birthdays: staying alive and remaining a smoker, staying alive and becoming a former smoker, dying in the state of being a smoker, or dying in the state of being a former smoker. The percentage of former smokers who do not experience the last of these events is the former smoker survival probability that we seek to calculate. We will illustrate this calculation for 25-year-old females, under the assumption of a 3 percent discount rate; the calculation for males or other discount rates or age categories would be analogous.

We again consider one hundred thousand female smokers at their 24th birthdays. According to the National Health Interview Survey (Ref. 128), 3.4 percent of them will become former smokers by their 25th birthdays. Following Sloan *et al.,* we use the 1998 NHIS and define former smokers as individuals who quit at least 5 years in the past. Sloan *et al.*'s life tables indicate that another 61 of the original one hundred thousand will die before their 25th birthdays; all 61 die in the state of being smokers (because no time has elapsed since they were smokers at the definitional age of 24). This leaves 96,540 who are alive and still smoking and 3,399 who are living former smokers at the 25th birthday.

Sloan *et al.*'s typical smoker life table indicates that 63 of these 25-year-old survivors will die before their 26th birthdays; we must calculate how many of them die in the state of being smokers and how many in the state of being former smokers. To find death probabilities for those individuals who are still smoking at age 25, we look to Sloan *et al.*'s life table for *lifetime* smokers. Whereas the typical smoker life table shows survival patterns for individuals who smoke at age 24 and may quit sometime later in life, the lifetime smoker life table isolates survival patterns for individuals who smoke at age 24 and continue to a specific age. The lifetime smoker life table will begin to diverge from the typical life table at later ages, but for birthdays 25 and 26, the results are once again 99,939 and 99,876 survivors; therefore, the percentage of 25-year-old female smokers who survive to birthday 26 is 99,876/99,939. Multiplying this percentage by the 96,540 smokers alive at birthday 25 yields 61 deaths. Therefore, two (=63 − 61) deaths of former smokers are expected between birthdays 25 and 26, and the age-specific former smoker survival probability is 1 − (2/3,399) = 0.99937. (This technique for estimating former smoker survival probability does not distinguish between recent quitters and those who quit many years ago. Not making this distinction, which becomes increasingly important the further beyond age 25 we consider, will result in our estimates of cessation-related life expectancy benefits being too great for those who quit at an advanced age and too low for those who quit at an early age.)

To find the expected number of life-years gained for a female who quits smoking at age 25, we subtract from 0.99937 the survival probability for a smoker of the same age (calculated from Sloan *et al.*'s typical smoker life table), then multiply by the discounted number of life-years lost if death occurs at age 25 (previously found to be 29.8), and finally add the expected value of life-years gained by quitting at age 26, discounted 1 year. Because there is no extension of life brought about by quitting at age 100, this addition is feasible for age 99, and then for age 98, and so on back to age 25. The final result for females who quit smoking at age 25 is 0.081 discounted life-years saved.

For the year 2013, we multiply our estimated age-specific expected discounted life-years saved by the cohort sizes (for ages 18 and above) projected by the U.S. Census Bureau (Ref. 130). For years 2014–31, we multiply our estimated age-specific expected discounted life-years saved by the cohorts that would not have been included in our 2013 calculation, specifically new 24-year-olds and older individuals whose cohorts grow from one year to another (for example, if the projected number of 35-year-olds in 2014 is greater than the projected number of 34-year-olds in 2013, the difference is included in the 2014 calculation). Finally, we estimate effects for individuals who are 18–23 in the year 2031 by discounting the present value of benefits accruing to 24-year-olds by the number of years until each cohort reaches that age threshold. Results are further multiplied by FDA's estimate of the rule-induced reduction in the U.S. smoking rate to yield our final estimate of the number of life-years saved by the regulation.

III. Technical Appendix X3: Timing of Benefits

FDA's estimated benefits appear as undiscounted streams in Table 45, Parts 1 through 12. Benefits are realized as late as 2113 because we calculate effects over lifetimes extending to age 100 for

cohorts aged 18 and above during the first 20 years (2012 to 2031) of the final rule's implementation.

Because many of our sources report only present values of smoking-related effects, estimating the timing of those effects requires us to make various assumptions. Changing those assumptions would change the results appearing in Table 45. Similarly, because many of our sources report present values calculated only with a discount rate of 3 percent, changing our assumptions about the timing of effects would change the present values we have reported at the 7 percent discount rate (an important exception being the present value of reduced mortality for 24-year-olds because Sloan *et al.*'s life tables allow us to know the timing of those benefits).

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Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 1

	2012	2013	2014	2015	2016	2017	2018	2019	2020
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	0.0	0.0	0.0	0.0	-0.1	-0.1	-0.1	-0.1	-0.2
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	0.0	10.4	20.9	31.3	41.7	52.0	62.2	72.2	82.1
Health Status, with VSLY = $212,615[a,c]	0.0	6.1	12.3	18.5	24.6	30.6	36.5	42.4	48.2
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	0.0	1.2	2.5	3.8	5.0	6.3	7.5	8.7	9.9
Medical Costs Reductions, Age > 24 in 2013[e]	0.0	21.7	21.7	21.7	21.7	21.7	21.7	21.6	21.6
Financial Effects[f]	0.0	1.1	1.6	2.1	2.6	3.1	3.6	4.1	4.6
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	0.0	4.9	4.9	5.0	5.1	5.2	5.2	5.3	5.4
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	0.0	2.8	2.9	2.9	3.0	3.0	3.1	3.1	3.2
Fire-Related Property Damage[i]	0.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	1.0
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	0.0	308.1	313.0	317.8	322.6	327.4	332.4	337.7	343.0
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	0.0	139.9	142.2	144.3	146.5	148.7	151.0	153.4	155.8

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 2

	2021	2022	2023	2024	2025	2026	2027	2028	2029
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	-0.2	-0.2	-0.1	-0.1	0.7	2.2	4.5	7.7	11.6
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	91.8	101.3	110.6	119.7	128.3	136.4	144.0	151.1	157.8
Health Status, with VSLY = $212,615[a,c]	53.9	59.6	65.3	71.1	77.1	83.2	89.3	95.4	101.6
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	11.0	12.2	13.4	14.6	15.8	17.0	18.3	19.5	20.8
Medical Costs Reductions, Age > 24 in 2013[e]	21.6	21.6	21.6	21.6	21.6	21.6	21.6	21.6	21.6
Financial Effects[f]	5.0	5.5	5.9	6.4	6.9	7.3	7.8	8.3	8.8
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	5.5	5.6	5.7	5.8	5.8	5.9	6.0	6.1	6.2
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	3.2	3.3	3.3	3.4	3.4	3.5	3.5	3.6	3.6
Fire-Related Property Damage[i]	1.0	1.0	1.0	1.0	1.0	1.1	1.1	1.1	1.1
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	348.4	353.9	359.4	365.1	370.8	376.6	382.6	388.7	394.8
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	158.2	160.7	163.3	165.8	168.4	171.1	173.8	176.5	179.3

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 3

	2030	2031	2032	2033	2034	2035	2036	2037	2038
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	16.5	22.2	29.0	36.7	45.4	55.7	67.5	81.0	96.4
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	163.9	169.5	174.6	179.2	183.3	186.8	189.6	191.8	193.4
Health Status, with VSLY = $212,615[a,c]	107.9	114.2	120.4	126.8	133.2	139.6	146.0	152.4	152.4
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	22.1	23.4	24.7	26.0	27.3	28.6	29.9	31.2	31.2
Medical Costs Reductions, Age > 24 in 2013[e]	21.5	21.5	21.4	21.2	21.1	21.0	20.8	20.6	20.5
Financial Effects[f]	9.4	9.9	10.4	11.0	11.6	12.2	12.8	13.5	13.9
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	6.3	6.4	6.3	6.3	6.2	6.1	6.1	6.0	6.0
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	3.7	3.7	3.7	3.7	3.6	3.6	3.5	3.5	3.5
Fire-Related Property Damage[i]	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	400.4	405.3	401.6	397.7	393.8	389.8	385.6	381.3	379.3
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	181.8	184.1	182.4	180.7	178.9	177.1	175.1	173.2	172.3

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 4

	2039	2040	2041	2042	2043	2044	2045	2046	2047
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	113.5	132.7	154.0	177.4	203.2	231.5	262.5	296.6	333.9
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	194.4	194.8	194.6	193.9	192.6	190.8	188.4	185.4	181.9
Health Status, with VSLY = $212,615[a,c]	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	31.2	30.3	29.3	28.3	27.4	26.5	25.5	24.6	23.7
Medical Costs Reductions, Age > 24 in 2013[e]	20.3	20.1	19.9	19.7	19.4	19.2	18.9	18.7	18.4
Financial Effects[f]	14.4	15.0	15.5	16.1	16.8	17.5	18.3	19.1	20.0
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	5.9	5.9	5.9	5.8	5.8	5.7	5.7	5.6	5.6
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	3.5	3.4	3.4	3.4	3.4	3.4	3.3	3.3	3.3
Fire-Related Property Damage[i]	1.1	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	377.2	374.9	372.6	370.1	367.3	364.3	361.3	358.3	355.1
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	171.3	170.3	169.2	168.1	166.8	165.5	164.1	162.7	161.3

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 5

	2048	2049	2050	2051	2052	2053	2054	2055	2056
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	374.5	418.7	465.6	515.5	568.4	624.4	683.5	745.7	811.1
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	177.9	173.4	168.4	163.1	157.3	151.2	144.9	138.3	131.5
Health Status, with VSLY = $212,615[a,c]	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	22.8	22.0	21.1	20.2	19.2	18.3	15.5	12.6	9.7
Medical Costs Reductions, Age > 24 in 2013[e]	18.1	17.7	17.4	17.0	16.6	16.3	15.9	15.5	15.0
Financial Effects[f]	21.0	22.1	23.3	24.5	25.8	27.2	28.6	30.0	31.6
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	5.5	5.5	5.4	5.3	5.3	5.2	5.1	5.0	5.0
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	3.2	3.2	3.2	3.1	3.1	3.0	3.0	2.9	2.9
Fire-Related Property Damage[i]	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	351.1	347.0	342.9	338.6	334.3	329.8	325.2	320.3	315.3
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	159.5	157.6	155.7	153.8	151.8	149.8	147.7	145.5	143.2

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 6

	2057	2058	2059	2060	2061	2062	2063	2064	2065
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	879.5	951.0	1,025.4	1,101.6	1,179.5	1,258.8	1,339.1	1,420.0	1,499.5
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	124.5	117.5	110.3	103.2	96.1	89.1	82.2	75.4	68.8
Health Status, with VSLY = $212,615[a,c]	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	6.8	3.9	1.1	-1.7	-4.5	-7.3	-10.1	-12.9	-14.7
Medical Costs Reductions, Age > 24 in 2013[e]	14.6	14.2	13.7	13.3	12.8	12.3	11.9	11.4	10.9
Financial Effects [f]	33.2	35.0	36.8	38.6	40.5	42.5	44.5	46.5	48.4
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	4.9	4.8	4.7	4.6	4.5	4.5	4.4	4.3	4.2
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	2.9	2.8	2.8	2.7	2.7	2.6	2.6	2.5	2.5
Fire-Related Property Damage[i]	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.7
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	310.2	304.9	299.5	294.1	288.5	283.0	277.5	272.0	266.4
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	140.9	138.5	136.1	133.6	131.0	128.5	126.0	123.5	121.0

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 7

	2066	2067	2068	2069	2070	2071	2072	2073	2074
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	1,577.2	1,652.5	1,725.2	1,794.6	1,857.9	1,914.4	1,963.6	2,004.9	2,037.9
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	62.5	56.5	50.7	45.2	40.0	35.2	30.8	26.8	23.1
Health Status, with VSLY = $212,615[a,c]	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	-16.6	-18.5	-20.4	-22.3	-24.2	-26.2	-28.2	-30.1	-32.1
Medical Costs Reductions, Age > 24 in 2013[e]	10.5	10.0	9.6	9.2	8.8	8.3	7.9	7.5	7.1
Financial Effects[f]	50.4	52.3	54.1	55.8	57.4	58.8	60.0	61.0	61.7
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	4.1	4.0	4.0	3.9	3.8	3.7	3.6	3.5	3.5
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	2.4	2.4	2.3	2.3	2.2	2.2	2.1	2.1	2.0
Fire-Related Property Damage[i]	0.7	0.7	0.7	0.7	0.7	0.7	0.6	0.6	0.6
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	261.0	255.9	250.9	245.9	240.7	235.3	230.1	225.0	220.2
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	118.5	116.2	113.9	111.7	109.3	106.9	104.5	102.2	100.0

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 8

	2075	2076	2077	2078	2079	2080	2081	2082	2083
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	2,056.2	2,060.2	2,050.8	2,028.8	1,995.5	1,951.7	1,898.6	1,837.1	1,768.2
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	19.8	16.8	14.1	11.8	9.7	8.0	6.5	5.2	4.1
Health Status, with VSLY = $212,615[a,c]	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	-34.1	-36.1	-38.1	-40.1	-40.1	-40.1	-40.1	-40.1	-40.1
Medical Costs Reductions, Age > 24 in 2013[e]	6.7	6.2	5.8	5.4	5.0	4.6	4.1	3.7	3.2
Financial Effects[f]	62.1	62.1	61.7	60.9	59.9	58.6	57.0	55.3	53.3
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	3.4	3.3	3.2	3.2	3.1	3.0	2.9	2.8	2.7
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	2.0	1.9	1.9	1.8	1.8	1.8	1.7	1.7	1.6
Fire-Related Property Damage[i]	0.6	0.6	0.6	0.6	0.5	0.5	0.5	0.5	0.5
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	215.4	210.6	205.7	200.9	195.8	190.7	185.3	179.8	174.3
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	97.9	95.6	93.5	91.2	89.0	86.6	84.1	81.7	79.2

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 9

	2084	2085	2086	2087	2088	2089	2090	2091	2092
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	1,692.7	1,611.9	1,526.4	1,436.4	1,342.4	1,245.4	1,147.1	1,047.9	948.1
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	3.3	2.6	2.0	1.5	1.1	0.9	0.8	0.6	0.5
Health Status, with VSLY = $212,615[a,c]	152.4	152.4	152.4	152.4	152.4	152.4	146.4	140.1	133.9
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	-40.1	-40.1	-40.1	-40.1	-40.1	-40.1	-38.5	-36.9	-35.3
Medical Costs Reductions, Age > 24 in 2013[e]	2.8	2.3	1.8	1.4	0.9	0.4	0.4	0.4	0.3
Financial Effects[f]	51.1	48.8	46.3	43.8	41.1	38.3	35.4	32.5	29.6
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	2.7	2.6	2.5	2.4	2.3	2.2	2.9	2.8	2.7
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	1.6	1.5	1.5	1.4	1.3	1.3	1.7	1.7	1.6
Fire-Related Property Damage[i]	0.5	0.5	0.4	0.4	0.4	0.4	0.5	0.5	0.5
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	168.9	163.4	157.9	152.4	146.8	141.1	185.9	179.5	173.0
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	76.7	74.2	71.7	69.2	66.7	64.1	84.4	81.6	78.6

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 10

	2093	2094	2095	2096	2097	2098	2099	2100	2101
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	848.2	748.5	651.8	558.6	469.4	384.8	305.1	237.3	180.5
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	0.4	0.3	0.2	0.2	0.1	0.1	0.1	0.0	0.0
Health Status, with VSLY = $212,615[a,c]	127.8	121.8	115.9	110.0	104.2	98.5	92.9	87.1	81.3
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	-33.7	-32.1	-30.5	-29.0	-27.4	-25.9	-24.5	-22.9	-21.4
Medical Costs Reductions, Age > 24 in 2013[e]	0.3	0.3	0.2	0.2	0.2	0.2	0.1	0.1	0.1
Financial Effects[f]	26.6	23.7	20.8	18.1	15.4	12.9	10.5	8.5	6.8
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	2.6	2.5	2.4	2.3	2.3	2.2	2.1	2.0	2.0
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	1.5	1.5	1.4	1.4	1.3	1.3	1.2	1.2	1.1
Fire-Related Property Damage[i]	0.5	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.3
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	166.5	160.3	154.4	149.0	143.7	138.6	133.8	129.0	124.2
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	75.6	72.8	70.1	67.7	65.3	63.0	60.8	58.6	56.4

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 11

	2102	2103	2104	2105	2106	2107	2108	2109	2110
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	133.8	96.4	67.2	45.0	28.7	17.2	9.5	4.7	1.9
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Health Status, with VSLY = $212,615[a,c]	75.3	69.3	63.2	57.0	50.8	44.5	38.3	32.0	25.6
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	-19.8	-18.2	-16.6	-15.0	-13.4	-11.7	-10.1	-8.4	-6.8
Medical Costs Reductions, Age > 24 in 2013[e]	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Financial Effects[f]	5.3	4.2	3.2	2.5	1.9	1.4	1.1	0.8	0.6
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	1.9	1.8	1.7	1.6	1.6	1.5	1.4	1.2	1.0
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	1.1	1.0	1.0	1.0	0.9	0.9	0.8	0.7	0.6
Fire-Related Property Damage[i]	0.3	0.3	0.3	0.3	0.3	0.3	0.2	0.2	0.2
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	119.1	113.9	108.8	103.8	98.7	93.6	88.0	74.5	60.9
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	54.1	51.8	49.4	47.1	44.8	42.5	40.0	33.8	27.6

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 12

	2111	2112	2113
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	0.5	0.0	0.0
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	0.0	0.0	0.0
Health Status, with VSLY = $212,615[a,c]	19.3	12.9	6.4
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	-5.1	-3.4	-1.7
Medical Costs Reductions, Age > 24 in 2013[e]	0.0	0.0	0.0
Financial Effects[f]	0.4	0.3	0.1
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	0.7	0.5	0.3
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	0.4	0.3	0.2
Fire-Related Property Damage[i]	0.1	0.1	0.1
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	47.2	33.4	19.6
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	21.4	15.2	8.9

[a] Numbers in this row may be multiplied by 0.5 to produce results for VSLY=$106,308 or by 1.5 to produce results for VSLY=$318,923.
[b] Also includes individuals who turn 24 between 2013 and 2031 but are first exposed to graphic warning labels at later ages due to immigration. Underlying assumptions discussed in detail in Technical Appendix X2.
[c] Underlying assumption: Sloan et al.'s present value of years with fair/poor health status distributed equally over ages 24 to 100. Result: this row shows benefits being accrued in a pattern somewhat less concentrated in the middle years of life than the likely reality. Because Sloan et al. report undiscounted effects of 2.69 years for females and 1.41 year for males, and discounting reduces the effects to 1.27 and 0.90 years, this concentration, on average, centers on females' forty-ninth birthdays and males' thirty-ninth birthdays.
[d] Underlying assumption: Sloan et al.'s medical cost present value distributed equally within age bins (24-50, 51-64 and 65+).
[e] Also includes individuals who turn 24 between 2013 and 2031 but are first exposed to graphic warning labels at later ages due to immigration. Underlying assumption: Sloan et al.'s medical costs present value distributed equally over ages 24 to 100. Result: this row shows benefits being accrued somewhat later and in lesser amounts than the likely reality for relatively young quitters and somewhat earlier and in greater amounts than the likely reality for relatively old quitters.
[f] Includes Social Security outlays, income taxes on Social Security-taxable earnings, defined benefit private pension outlays and life insurance outlays. Underlying assumption: net financial effect distributed over time in the same pattern as the sum of mortality, morbidity and medical cost effects.
[g] Underlying assumption for quitters aged 25 and above: Sloan et al.'s cigarette consumption present value distributed equally over ages 24 to 100. Result: this row shows benefits being accrued somewhat later and possibly in slightly greater amounts than the likely reality. Fire-related death loss is a present value, calculated at the time of death with a discount rate of 3 percent, of future VSLY.
[h] Underlying assumption for quitters aged 25 and above: Sloan et al.'s cigarette consumption present value distributed equally over ages 24 to 100. Result: this row shows benefits being accrued somewhat later and possibly in slightly greater amounts than the likely reality. Fire-related death loss is a present value, calculated at the time of death with a discount rate of 7 percent, of future VSLY.
[i] Underlying assumption for quitters aged 25 and above: Sloan et al.'s cigarette consumption present value distributed equally over ages 24 to 100. Result: this row shows benefits being accrued somewhat later and possibly in slightly greater amounts than the likely reality.
[j] Numbers in this row may be multiplied by approximately 0.496 to produce results for VSLY=$106,308 or by approximately 1.504 to produce results for VSLY=$318,923.
[k] Numbers in this row may be multiplied by approximately 0.520 to produce results for VSLY=$106,308 or by approximately 1.500 to produce results for VSLY=$318,923.

IV. Technical Appendix X4: Timing of Costs

Table 46.--Undiscounted Stream of Costs, Low Estimate ($ mil), Part 1

	2012	2013	2014	2015	2016	2017	2018	2019	2020
Private Sector									
Labeling Change	272.5								
Market Testing	1.5								
Point-of-Sale Advertising	45.4								
Continuing Admin and RK		0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Subtotal	319.5	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Government									
FDA	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Subtotal	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	325.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6

Table 46.--Undiscounted Stream of Costs, Low Estimate ($ mil), Part 2

	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Private Sector											
Labeling Change											
Market Testing											
Point-of-Sale Advertising											
	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Subtotal	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Government											
FDA	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Subtotal	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	6.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6

Table 47.--Undiscounted Stream of Costs, Medium Estimate ($ mil), Part 1

	2012	2013	2014	2015	2016	2017	2018	2019	2020
Private Sector									
Labeling Change	295.2								
Market Testing	2.1								
Point-of-Sale Advertising	45.4								
Continuing Admin and RK		0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Subtotal	342.7	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Government									
FDA	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Subtotal	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	348.9	6.8	6.8	6.8	6.8	6.8	6.8	6.8	6.8

Table 47.--Undiscounted Stream of Costs, Medium Estimate ($ mil), Part 2

	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Private Sector											
Labeling Change											
Market Testing											
Point-of-Sale Advertising											
		0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Subtotal	0.0	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Government											
FDA	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Subtotal	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	6.2	6.8	6.8	6.8	6.8	6.8	6.8	6.8	6.8	6.8	6.8

Table 48.--Undiscounted Stream of Costs, High Estimate ($ mil), Part 1

	2012	2013	2014	2015	2016	2017	2018	2019	2020
Private Sector									
Labeling Change	464.8								
Market Testing	8.2								
Point-of-Sale Advertising	45.4								
Continuing Admin and RK		0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
Subtotal	518.4	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
Government									
FDA	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Subtotal	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	524.6	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1

Table 48.--Undiscounted Stream of Costs, High Estimate ($ mil), Part 2

	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Private Sector											
Labeling Change											
Market Testing											
Point-of-Sale Advertising											
	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
Subtotal	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
Government											
FDA	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Subtotal	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1

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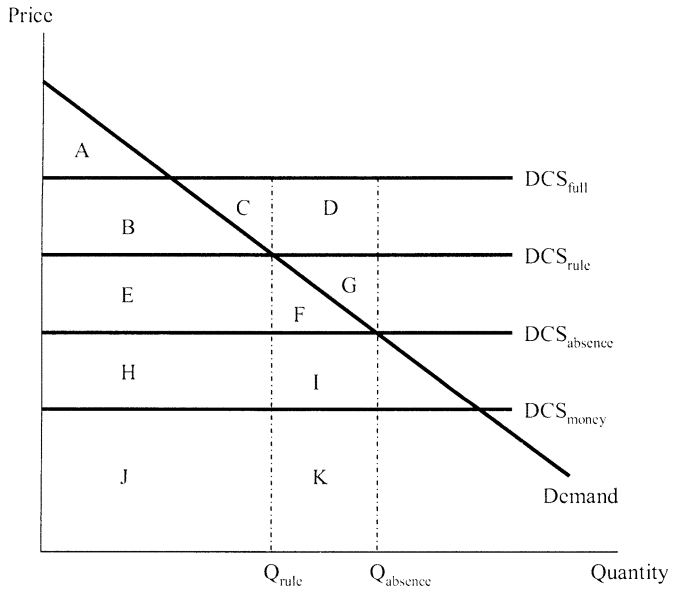
V. Technical Appendix X5: Additional Diagrams on Benefits

Consumer Surplus Model. The benefits estimated in sections XI.D.2.b.ii, XI.D.2.b.iii, XI.D.2.b.iv and XI.D.2.b.v overstate, all else held equal, the net internal (*i.e.,* intrapersonal) benefits (or costs, in the case of section XI.D.2.b.v) of reduced smoking because they include only the increased welfare from improved health and expected longevity (and decreased welfare due to subsidy loss) and do not account for any lost consumer surplus [21] associated with the activity of smoking. In the Preliminary Regulatory Impact Analysis (see page 75 FR 69524 at 69544), FDA adjusted benefits estimates with a 50 percent consumer surplus reduction, based on a model created by Cutler (Ref. 134). Several comments on the proposed rule expressed concern about the appropriateness of Cutler's assumptions, so FDA has revised the model to make it more applicable to the present analysis. Our revised model is illustrated in Figure E1.

[21] The difference between what a consumer would be willing to pay for a good or service and what that consumer actually has to pay.

Figure E1. The Market for Smoking, Before and After Rule Implementation



We begin with a downward-sloping demand for typical lifetime smoking. A negative relationship between price and consumption of cigarettes has been demonstrated empirically many times over (Chaloupka and Warner (Ref. 162) review this literature).

The height of line DCS_{full} marks the full cost, including the cost of adverse health and life expectancy effects, of typical lifetime smoking (thus, the ''Discounted Cost of Smoking'' or DCS), while the height of line DCS_{money} marks only the after-tax price of cigarettes. The height difference between these two lines is the sum of the per-person effects we calculated in sections XI.D.2.b.ii, XI.D.2.b.iii and XI.D.2.b.iv. Also belonging in DCS_{full} are the effects calculated in section XI.D.2.b.v because the concept of the full cost of smoking, as used in the model, is defined from the private perspective of the smoker (and thus it is irrelevant whether or not there is someone else in society who experiences an effect that offsets the cost or benefit experienced by the smoker—which is what distinguishes the entries in Tables 22 and 23 from the effects in sections XI.D.2.b.ii, XI.D.2.b.iii and XI.D.2.b.iv). While the elements in Tables 22 and 23 do contribute to DCS_{full}, we posit that they should not be thought of as included in DCS_{money} because they are intricately related to the mortality and morbidity effects of smoking that, unlike the after-tax price of cigarettes, are likely characterized by time inconsistency, incomplete information or other sources of market failure.

Society will be at the intersection of Demand and DCS_{money} if the health costs associated with smoking are not known or, if known, cannot be ''internalized'' and incorporated into consumption decisions. The current widespread awareness that smoking poses health risks and the significant decline in smoking rates over the past 50 years make it highly implausible that actual consumption is near that hypothetical level. The intersection of the Demand line and DCS_{full} represents the other extreme. At that hypothetical level, consumers are fully aware of all known risks and have internalized all health costs and incorporated them into consumption decisions. The economic models and empirical studies of addiction, self–control, and time inconsistency (which we discuss in detail in our response to comments on the preliminary analysis) strongly suggest that health costs are not fully internalized; the behaviors that lead to less-than-full internalization appear to be common. In surveys, many smokers express a desire to quit and report that they have tried to stop smoking. The demand for various aids to smoking cessation provides further evidence of less-than-full internalization. Moreover, the immature judgments, short time horizons and lack of self-control of most children and adolescents—who make up the vast majority of new smokers—suggest that policy interventions that prevent initiation and encourage cessation can increase social welfare.

For these reasons, we find it implausible that actual consumption is at the intersection of Demand and DCS_{full}. The number of current smokers is therefore found at the intersection of Demand with a line falling somewhere between DCS_{full} and DCS_{money}. We have drawn this as line $DCS_{absence}$. Our finding that the graphic warning label regulation will reduce smoking rates is represented by an upward shift of this line to DCS_{rule}. (This may seem less intuitive to some readers than shifting the demand curve—which is the approach taken by Weimer *et al.* (Ref. 181)—but the two analytic methods will produce equivalent results, as we illustrate below.) The intersections of $DCS_{absence}$ and DCS_{rule} with the demand curve show the number of smokers, $Q_{absence}$ and $Q_{rule,}$ in the absence and in the presence of the final rule.

In the absence of the final rule, total cost, including health costs, for smokers is shown by the sum of areas *B* through *K*. We reiterate that, even though consumers do not internalize all costs upfront, they do ultimately incur them. The gross value smokers place on cigarette consumption (known as willingness-to-pay) is the area under the demand curve as far right as $Q_{absence}$, or $A+B+E+F+H+I+J+K$. The net value to smokers of cigarette consumption is thus $(A+B+E+F+H+I+J+K) - (B+C+D+E+F+G+H+I+J+K) = A - (C+D+G)$.

In the presence of the final rule, total expenditure, including health costs, by smokers is $B+C+E+H+J$. Smokers' willingness-to-pay is the area under the demand curve as far right as Q_{rule}, or $A+B+E+H+J$. The net value to smokers of cigarette consumption is thus $(A+B+E+H+J) - (B+C+E+H+J) = A - C$. As a result, the effect of the rule is to increase net value by $(A - C) - [A - (C+D+G)] = D+G$.

The calculations appearing in sections XI.D.2.b.ii, XI.D.2.b.iii, XI.D.2.b.iv and XI.D.2.b.v each consist of multiplying ($Q_{absence} - Q_{rule}$) by some portion of ($DCS_{full} - DCS_{money}$); therefore, summing the results of D2b.ii, D2b.iii, D2b.iv and D2b.v produces an estimate of ($D+F+G+I$). Because we have already established that the benefit of the rule is ($D+G$), reporting the unadjusted sum of results from sections XI.D.2.b.ii, XI.D.2.b.iii, XI.D.2.b.iv and XI.D.2.b.v would cause us to overestimate the benefits of the final rule by an amount equal to $(D+F+G+I)-(D+G) = (F+I)$. As drawn in Figure E1, ($F+I$) is approximately 50 percent of the unadjusted estimate, ($D+F+G+I$). FDA does not claim that 50 percent is the correct ratio; the correct ratio of ($F+I$) to ($D+F+G+I$) is determined by the shape of the demand curve as it divides areas F and G and, more pertinently, by the relative height differences between DCS_{full} and DCS_{rule} and between $DCS_{absence}$ and DCS_{money}. ($DCS_{full} - DCS_{rule}$) may be much greater than ($DCS_{absence} - DCS_{money}$) or it may be much less, yielding a ratio that may be near zero or may be near 100 percent, depending on the starting height of $DCS_{absence}$ and the size of the policy-induced reduction in smoking.

We now parameterize this model using the literature on the economics of habits and addiction. (We note, however, that rigorous quantitative welfare analyses of tobacco control interventions are rare in published, peer-reviewed literature, so the estimates generated below should not be viewed as definitive.) First, the Robert Wood Johnson Foundation (Ref. 137) reports that, as of 2009, State and Federal taxes made up 40.4 percent of the total retail price of cigarettes. With the Federal cigarette excise tax being $1.01 per pack (Ref. 164) and the population-weighted average State tax being $1.33 per pack (Ref. 165, with population weights from Ref. 130), we estimate the average after-tax price of a pack of cigarettes, or the height of DCS_{money}, to be $5.78. FDA's analysis in section XI.D.2.b of the benefits of smoking reduction has produced an estimate of discounted internal health and financial effects (reduced mortality, morbidity, medical costs and implicit smoking subsidy) that ranges from $2.10 billion to $27.80 billion in total, or from $4.56 to $27.69 per pack; this range indicates the range of potential height differences between DCS_{full} and DCS_{money}. We can derive the heights of the remaining DCS curves from a simulation conducted by Gruber and Köszegi (Ref. 104), in which they estimate the tax rate that would allow time-inconsistent smokers to consume the quantity that would be optimal under perfect rationality. Because this quantity is found at the intersection of the demand curve and DCS_{full}, Gruber and Köszegi's tax result provides an estimate of $DCS_{full} - DCS_{absence}$. Gruber and Köszegi first estimate an internal health cost of $30.45 per pack. From this, they calculate an internality tax that ranges from $0.98 to $2.89 (depending on technical parameters of their model), with an average of $2.17. FDA's internal health and financial cost estimates differ from Gruber and Köszegi's in a number of respects, including discount rate and use of a VSLY rather than value of a statistical life approach. We therefore scale the $2.17 internality tax estimate according to the ratio between our internal health and financial cost estimates and the $30.45 result found by Gruber and Köszegi; this produces internality tax estimates ranging from $0.33 to $1.98. Subtracting these values from our estimates of DCS_{full} yields estimates of $DCS_{absence}$ ranging from $10.01 to $31.49. Knowing $DCS_{absence}$ and $Q_{absence}$, we can use a Gruber and Köszegi elasticity estimate, -0.803, to find the height of DCS_{rule}. This calculation yields estimates of the difference between DCS_{rule} and DCS_{full} that range from $0.27 to $1.81. If we assume a linear demand curve (in which case F will be 50 percent of the sum of F and G), this indicates that consumer surplus loss offsets roughly 93 percent of rule-induced internal health benefits. An analogous calculation using the $7.50 per pack tax suggested by Gruber (Ref. 133) indicates that consumer surplus loss offsets roughly 76 percent of rule-induced internal health benefits.

Figures E2 and E3 illustrate the underlying model for the benefits analysis and the uncertainty associated with the changes in consumer surplus resulting from the final rule and other tobacco control policies. The diagrams are elaborations on Figure E1, and lines and areas should be interpreted as discussed in the explanation of that figure. (Full internalization in Figure E2 corresponds to DCS_{full} in Figure E1; no internalization in Figure E2 corresponds to DCS_{money} in Figure E1.) Both of the diagrams below show the effects on lifetime smoking of differing degrees of average internalization of the full costs of smoking. Figure E2 shows a rise in the full price (equal to the money price plus the internalized cost), while Figure E3 shows a downward shift in demand equal to the level where all costs are internalized; both diagrams illustrate how the market evolves as it moves leftward from the no-internalization equilibrium to the full-internalization equilibrium. We note that the net internal benefits to smokers of smoking reductions, shown as shaded triangles or trapezoids above the full-internalization demand curve, are the same size in each diagram. Moreover, the area representing benefits decreases in size as the size of the smoking population decreases. We assume that the market is currently at some intermediate point given by the intersection of one of the dashed (partial internalization) price lines with the solid demand curve or the intersection of one of the dashed (partial internalization) demand curves with the solid money price line, but we are not able to definitively estimate where that point is today or where it will be after this final rule takes effect.

Figure E2. Smoking Market Illustrated with Shifting Full Cost Lines

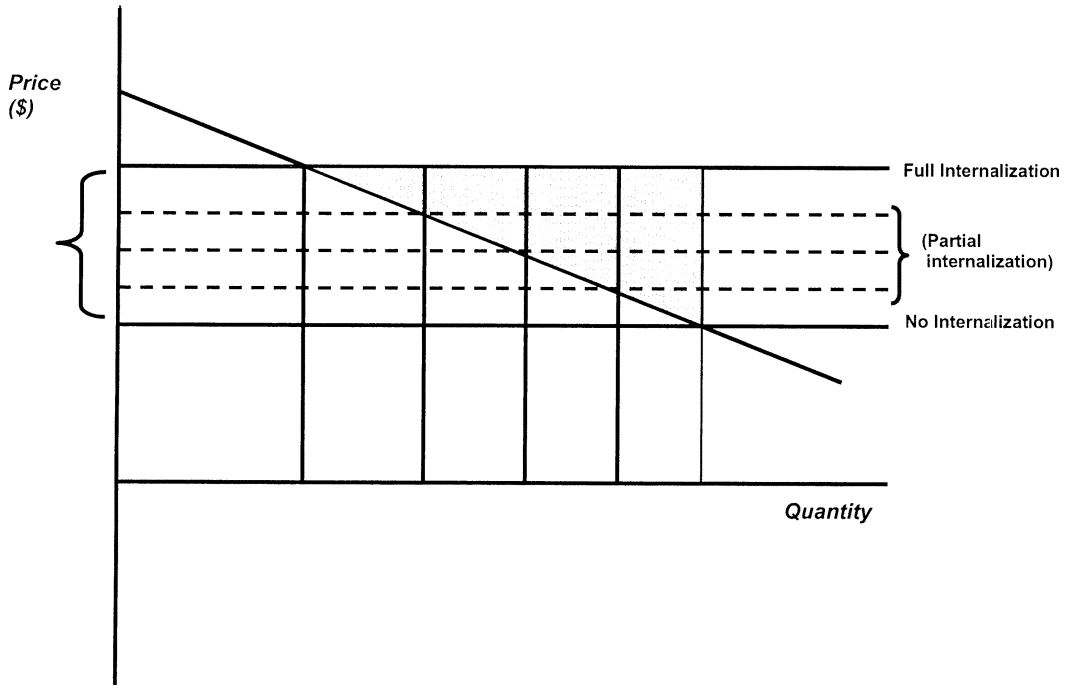
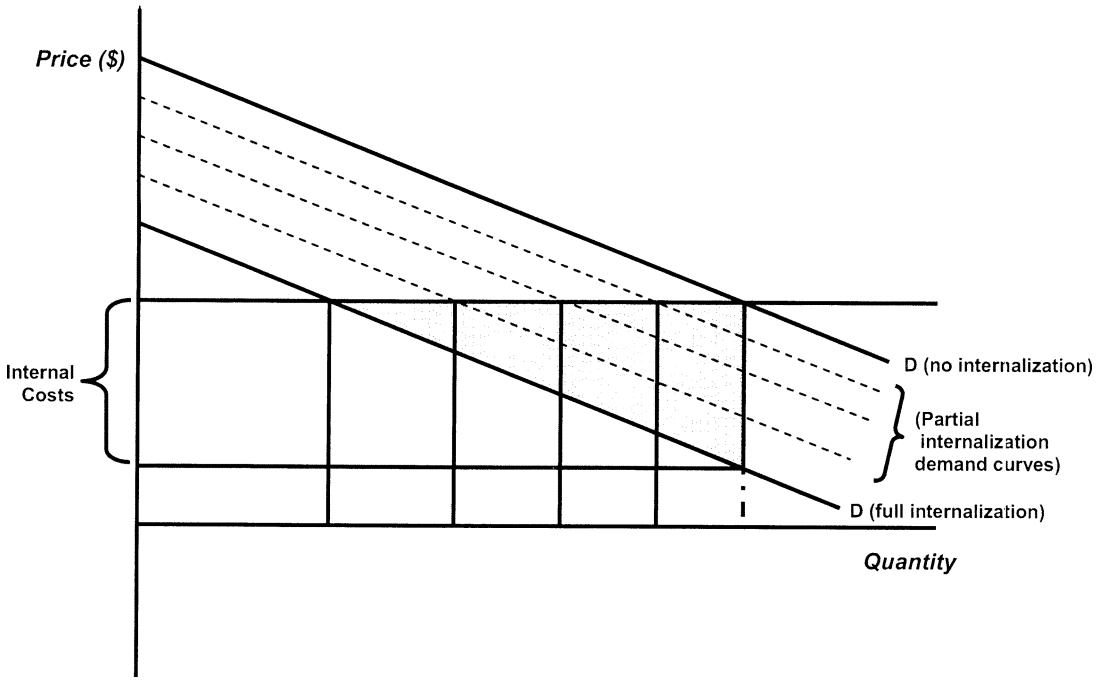


Figure E3. Smoking Market Illustrated with Shifting Demand Curves



VI. Technical Appendix X6: Uncertainty Analysis

Estimation of the effectiveness of the rule (on reducing the future U.S. smoking rate) is subject to a large uncertainty that is not fully reflected in the benefits estimates appearing in the preceding sections, which only reflect different estimates of the VSLY and different discount rates. In this section, we show the uncertainty associated with our estimate of the effectiveness of the rule.

A. Alternative Estimation of Smoking Rate Reduction

Our primary estimate, that the U.S. smoking rate will decrease by 0.088 percentage points, was calculated in the following steps. First, we found the decrease in Canadian smoking rates

since 1994 over and above what would have been expected using the pre-2001 trend and accounting for the effect of excise tax changes. We then subtracted the analogous unexplained decrease in the U.S. smoking rate over the same period. This second step was driven by the idea that the U.S. experience could proxy for recent social or policy changes (such as public smoking restrictions) that may have had effects on Canada's smoking rate and thus needed to be subtracted in order to isolate the effect of graphic warning labels. The last step was to calculate the difference between United States and Canadian unexplained decreases in smoking before and after graphic warning labels were introduced in Canada. We attributed the remaining unexplained difference to graphic warning labels.

However, the U.S. social and policy climate may have been so different from Canada's during the years 1994–2009 that this proxy is inappropriate. To account for this possibility, we calculate the unexplained difference in Canadian smoking rates before and after graphic warning labels were introduced, this time omitting any U.S. adjustments. We assume that antismoking policies and programs other than the graphic warning labels are incorporated in the pre-2001 trend, with no additional effects of these variables occurring after the introduction of graphic warning labels. This approach indicates that graphic warning labels may have been responsible for a 0.574 percentage point decrease in the Canadian smoking rate. If the rule were to achieve this effectiveness level in the United States, benefits would be approximately six times larger than those reported earlier in this analysis. For example, our benefits estimates calculated with a VSLY of $318,923 and a net-to-gross benefits ratio of 90 percent rise from $1,681.0 million with a 3 percent discount rate and $517.5 million with a 7 percent discount rate (see Table 9b) to $10,916.6 and $3,360.7 million. We use these last two numbers as global upper bounds in Table 1.

Although both of the estimation methods discussed thus far lead to the conclusion that graphic warning labels will reduce smoking rates, FDA has had access to very small data sets, so our effectiveness estimates are in general not statistically distinguishable from zero; we therefore cannot reject, in a statistical sense, the possibility that the rule will not change the U.S. smoking rate. Therefore, the appropriate lower bound on benefits is zero. Ranges of benefits, representing the zero-effect case and the Canada-only modeling approach, appear in Table 49. The wide ranges shown in the table highlight the uncertainty inherent in our approach.

Table 49.--Ranges of Benefits ($ billion)

	VSLY=$106,308		VSLY=$212,615		VSLY=$318,923	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Present Value	[0 , 33.8]	[0 , 9.0]	[0 , 60.9]	[0 , 15.2]	[0 , 88.0]	[0 , 21.2]
Annualized Value (Over Twenty Years)	[0 , 2.3]	[0 , 0.8]	[0 , 4.1]	[0 , 1.4]	[0 , 5.9]	[0 , 2.0]

B. Monte Carlo Simulation

In addition to the uncertainty surrounding the effectiveness of graphic warning labels at reducing smoking rates, the other principal uncertainty in our benefits analysis is the value to smokers of cessation or avoided initiation. As discussed in section XI.D.2, we use two methods and several net-to-gross benefits ratios to produce a range of value estimates. For every percentage point reduction in the national smoking rate, these estimates become $4.2 to $281.6 billion (with a 3 percent discount rate) or $1.3 to $61.1 billion (with a 7 percent discount rate). Similarly, for every percentage point reduction in the national smoking rate, estimates of benefits accruing to the general public (including fire loss and financial effects) range from $6.1 to $14.7 billion (with a 3 percent discount rate) or $4.3 to $11.6 billion (with a 7 percent discount rate). Details appear in Table 50.

Table 50.--Benefits Ranges, Per Percentage Point Reduction in Smoking Rate ($ mil)

	3% Discount Rate			7% Discount Rate		
	VSLY= $106,308	VSLY= $212,615	VSLY= $318,923	VSLY= $106,308	VSLY= $212,615	VSLY= $318,923
Accruing to Dissuaded Smokers:						
Lower Bound	4,191.0	4,191.0	4,191.0	1,489.5	3,007.7	3,648.8
Upper Bound	96,196.9	188,907.5	281,618.1	22,386.4	42,260.2	62,134.0
Accruing to General Public:						
Lower Bound	6,097.1	6,982.8	7,868.6	2,017.9	2,257.9	2,497.9
Upper Bound	12,895.9	13,781.7	14,667.4	6,230.0	6,470.0	6,710.0

We estimate the 90th percentile range for the present and annualized values of total benefits with a Monte Carlo simulation. We model the distribution of the decline in smoking rates with a non-parametric bootstrap, in which we draw from discrete uniform distributions an individual year's United States-Canada adjusted smoking rate difference from the graphic warning label period (in Canada) and an individual year's difference from the pre-graphic warning label period. To account for uncertainty in the value to dissuaded smokers of cessation or avoided initiation, we use for each discount rate and VSLY a uniform distribution running from the lower

bound estimate to the upper bound estimate, as shown in Table 50. Benefits accruing to the general public are modeled analogously, with a uniform distribution bounded below and above by the values appearing in the table. We run 100,000 iterations for each simulation and report our results in Table 51. Both positive and negative results appear in the table because some paired-year United States-Canada differences show graphic warning labels decreasing the Canadian smoking rate and some paired-year differences show them increasing the smoking rate. (The second finding is almost certainly due to survey noise. More specifically, ordinary sampling variation will cause the percentage of smokers contained in a survey sample to change from one year or country to the next; this is separate from any underlying change in the true smoking rate. Depending on the sizes and directions of the relative changes, a comparison of country-year pairs can show the smoking rate increasing even when it has actually decreased, or vice versa. Because we expect this survey noise to overestimate the smoking rate change in some years and underestimate it in others, in our primary estimate, we take an average over all the years for which we have data in order to estimate as reliably as possible the true underlying change.) The wide differences in benefits shown in the table highlight the uncertainty inherent in our analysis.

Table 51.--Monte Carlo Simulation Ranges of Benefits ($ billion)

	VSLY=$106,308		VSLY=$212,615		VSLY=$318,923	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Present Value	[-54.0 , 69.4]	[-14.3 , 18.1]	[-100.3 , 127.1]	[-24.2 , 30.9]	[-144.5 , 185.3]	[-35.5 , 43.9]
Annualized Value (Over 20 Years)	[-3.6 , 4.7]	[-1.3 , 1.7]	[-6.7 , 8.5]	[-2.3 , 2.9]	[-9.7 , 12.5]	[-3.3 , 4.1]

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Part III

Nuclear Regulatory Commission

10 CFR Parts 170 and 171

Revision of Fee Schedules; Fee Recovery for Fiscal Year 2011; Final Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 170 and 171

RIN 3150–AI93

[NRC–2011–0016]

Revision of Fee Schedules; Fee Recovery for Fiscal Year 2011

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is amending the licensing, inspection, and annual fees charged to its applicants and licensees. The amendments are necessary to implement the Omnibus Budget Reconciliation Act of 1990 (OBRA–90), as amended, which requires the NRC to recover through fees approximately 90 percent of its budget authority in Fiscal Year (FY) 2011, not including amounts appropriated from the Nuclear Waste Fund (NWF), amounts appropriated for Waste Incidental to Reprocessing (WIR), and amounts appropriated for generic homeland security activities. Based on the Department of Defense and Full-Year Continuing Appropriations Act, 2011, signed by the President on April 15, 2011, the NRC's required fee recovery amount for the FY 2011 budget is approximately $915.8 million. After accounting for billing adjustments, the total amount to be billed as fees is approximately $916.2 million.

DATES: *Effective Date:* August 22, 2011.

ADDRESSES: You can access publicly available documents related to this final rule using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr.resource@nrc.gov.*
- *Federal Rulemaking Web Site:* Public comments and supporting materials related to this final rule can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2011–0016. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668; e-mail: *Carol.Gallagher@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Rebecca Erickson, Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7126, e-mail: *Rebecca.Erickson@NRC.gov.*

SUPPLEMENTARY INFORMATION:

I. Background
II. Response to Comments
III. Final Action
A. Amendments to 10 CFR Part 170: Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, As Amended
B. Amendments to 10 CFR Part 171: Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC
IV. Voluntary Consensus Standards
V. Environmental Impact: Categorical Exclusion
VI. Paperwork Reduction Act Statement
VII. Regulatory Analysis
VIII. Regulatory Flexibility Analysis
IX. Backfit Analysis
X. Congressional Review Act

I. Background

The NRC is required each year, under OBRA–90 (42 U.S.C. 2214), as amended, to recover approximately 90 percent of its budget authority, not including amounts appropriated from the NWF, amounts appropriated for WIR, and amounts appropriated for generic homeland security activities (non-fee items), through fees to NRC licensees and applicants. The NRC receives 10 percent of its budget authority (not including non-fee items) from the general fund each year to pay for the cost of agency activities that do not provide a direct benefit to NRC licensees, such as international assistance and Agreement State activities (as defined under Section 274 of the Atomic Energy Act of 1954, as amended).

The NRC assesses two types of fees to meet the requirements of OBRA–90. First, user fees, presented in Title 10 of the Code of Federal Regulations (10 CFR) part 170 under the authority of the Independent Offices Appropriation Act of 1952 (IOAA) (31 U.S.C. 9701), recover the NRC's cost of providing special benefits to identifiable applicants and licensees. For example, the NRC assesses these fees to cover the cost of inspections, applications for new licenses and license renewals, and requests for license amendments. Second, annual fees, presented in 10 CFR part 171 under the authority of OBRA–90, recover generic regulatory costs not otherwise recovered through 10 CFR part 170 fees.

In accordance with OBRA–90, $26 million of the agency's budgeted resources for generic homeland security activities are excluded from the NRC's fee base in FY 2011. These funds cover generic activities such as rulemakings, development of guidance documents that support entire license fee classes or classes of licensees, and major information technology systems that support tracking of source materials. Under its IOAA authority, the NRC will continue to charge part 170 fees for all licensee-specific homeland security-related services provided, including security inspections and security plan reviews.

On April 15, 2011, the President signed the Department of Defense and Full-Year Continuing Appropriations Act, 2011 (Pub. L. 112–10). In the Act, as adjusted by the rescission discussed in Section 1119(a), Congress appropriated $1,054.1 million to the NRC to carry out its mission in FY 2011. This is $0.5 million more than the amount used to develop the FY 2011 proposed rule (76 FR 14748; March 17, 2011). The total amount NRC is required to recover in fees for FY 2011 is approximately $915.8 million, which is increased by approximately $0.4 million to account for billing adjustments (*i.e.* expected unpaid invoices, payments for prior year invoices), resulting in a total of approximately $916.2 million to be billed as fees in FY 2011.

The amount of the NRC's required fee collections is set by law, and is, therefore, outside the scope of this rulemaking. In FY 2011, the NRC's total fee recovery amount has increased by $3.6 million from FY 2010. The FY 2011 budget supports activities associated with the safe and secure operations of civilian nuclear power reactors, research and test reactors, various fuel facilities, use of nuclear materials, and storage and transportation of spent nuclear fuel. The FY 2011 budget was allocated to the fee classes that the budget activities support. The annual fees for power reactors and uranium recovery facilities have decreased while fees for spent fuel storage facilities, nonpower reactors, fuel facilities, most materials users, and Department of Energy's (DOE) uranium recovery and transportation activities have increased. Another factor affecting

the amount of annual fees for each fee class is the estimated collection under part 170, discussed in Section III, ''Final Action,'' of this document.

II. Response to Comments

The NRC published the FY 2011 proposed fee rule on March 17, 2011 (76 FR 14748) to solicit public comment on its proposed revisions to 10 CFR parts 170 and 171. By the close of the comment period (April 18, 2011), the NRC received seven comments that were considered in this fee rulemaking. The comments have been grouped by issues and are addressed in a collective response.

A. Specific Part 170 Issues

1. Hourly Rate Increase

Comment. Several commenters were opposed to the increase in the NRC's hourly rate. One commenter requested further explanation for the increase in agency corporate support and Inspector General (IG) recoverable budgeted resources, which he attributed to the main reason for the hourly rate increase. Some commenters noted that NRC's hourly rate greatly exceeds the rate charged by industry consultants and the 5.4 percent hourly rate increase exceeds the current rate of inflation.

Response. The NRC's hourly rate is based on budgeted costs and must be established each year to meet the NRC's fee recovery requirements. In response to the comment attributing the hourly rate increase to the increase for agency corporate support and IG recoverable budgeted resources, as discussed in the proposed rule, in FY 2011 the NRC revised its budget structure. This new structure allows the agency to accurately identify all of its direct, indirect, and overhead costs. The increase for agency corporate support budgeted resources was offset by the decrease in budgeted resources for mission indirect program support, which is shown in Section III.A.1. Table II, ''Hourly Rate Calculation.'' Consequently, the increase in the hourly rate is due to appropriately capturing the FY 2011 agency overhead budgeted resources, and a small reduction in the number of direct full-time equivalents (FTEs).

In response to comments that the NRC hourly rate increase exceeds the current rate of inflation and the rate is higher than private industry rates, the NRC's rate is calculated to recover all of the budgeted costs supporting the services provided under part 170, including all programmatic and agency overhead, which is consistent with the full cost recovery concept emphasized in Office of Management and Budget Circular No. A–25, ''User Charges.'' The NRC did not receive any comments suggesting ways to revise its hourly rate calculation methodology, and comments on previous rulemakings have consistently supported the NRC's efforts to collect more of its budget through part 170 fees-for-services rather than part 171 annual fees. Therefore, the NRC is retaining the hourly rate formula as presented in the FY 2011 proposed rule.

2. Multiple Hourly Rates

Comment. One commenter requested that the NRC consider developing different hourly rates to account for more complex licensing tasks (and corresponding allocation of NRC staff resources) and that commercial operators bear a greater portion of the fee recovery burden.

Response. The NRC has considered comments in previous fee rulemakings on multiple hourly rates. In the FY 1995 fee rule (60 FR 32218; June 20, 1995), the NRC replaced the one agency-wide professional hourly rate with two hourly rates based on ''cost center concepts'' used for budgeting purposes to separately, and more equitably, allocate the costs associated with the reactor and materials programs. In the FY 2007 fee rule (72 FR 31402; June 6, 2007), the NRC returned to the use of one hourly rate because there was no longer a significant difference in the two hourly rates. Further, the additional burden required to develop and provide annual review and oversight of a multiple hourly rate schedule that takes into account the complexity of a task would likely increase overhead costs, and thus be counterproductive. Therefore, the NRC is retaining the single hourly rate as presented in the FY 2011 proposed rule.

3. Flat Rates

Comment. Some commenters recommended implementing a schedule of costs using flat fees for common tasks for uranium recovery licensees. The commenters believe that flat rates would assist the industry in preparing their annual budgets and better anticipate costs.

Response. Part 170 ''flat'' license fees are fees charged for most material and import/export license applications and amendments. These fees are based on the average direct hours required to process the application or amendment, multiplied by the professional hourly rate established annually in part 170. The average processing time is determined through a biennial review of actual hours associated with processing these applications or amendments. The NRC has considered the commenters' recommendation to include common tasks for uranium recovery licensees in the part 170 ''flat'' license fees. Based on past experience, the NRC believes there would be a very limited number of licensing activities that would qualify for an average cost method. In addition, a ''flat'' rate would still need to be adjusted annually to reflect any change to the NRC's professional hourly rate. Thus, the NRC believes the implementation and oversight costs associated with ''flat'' fees for uranium recovery tasks would outweigh any potential benefit to NRC licensees. Therefore, the NRC is not considering the addition of any part 170 ''flat'' license fees in this final fee rule.

4. Improving Uranium Recovery Licensing Process

Comment. Some commenters stated that the NRC is invoicing excessive hourly charges to uranium recovery licensees. These commenters asserted that the excessive hourly charges could be eliminated by improving the NRC licensing process. One commenter representing current and prospective uranium recovery fee class licensees called for a revision to the proposed rule to require more efficient processing of services subject to hourly fees.

Response. NRC understands that costs for processing a license for new facilities can be expensive. However, the staff has attempted to minimize the impact of part 170 fees on applicants and licensees. For example, when new personnel are assigned to a license review, time will not be charged to an applicant or licensee until the staff has become familiar with the project. In addition, licensees are not charged for inspections during the period new uranium recovery employees are being trained. Although inefficiencies have occurred during past reviews, the staff is cognizant of the charges billed to applicants and licensees and attempts to use its time wisely.

Furthermore, in an effort to minimize review time, the NRC staff has increased its efforts to communicate licensing requirements for application submittals. For example, the staff has held or participated in at least 2 workshops each year since 2007, the latest of which was held in January 2011. The staff has also recently participated in a focus group meeting designed to resolve global issues and ultimately reduce application review time. Despite these outreach efforts, some uranium recovery applicants have provided applications or responses to requests for additional information that have been insufficient and resulted in longer review times and

higher fees. Applicants can reduce their costs by providing complete and well-organized applications that enable reviewers to easily perform the required analyses.

Finally, the NRC has begun to revise its guidance documents in order to assist applicants prepare better applications, and will continue efforts to ensure that the staff carries out its statutory obligations in an efficient manner. However, the efficiencies of NRC's regulatory activities and the manner in which NRC carries out its fiscal responsibilities are not addressed in this final rule because the NRC's budget and the manner in which the staff carries out its activities are outside the scope of this rulemaking.

5. Lack of Invoice Detail

Comment. Some commenters representing themselves or current and prospective uranium recovery licensees asserted that the NRC's invoices consistently lack sufficient detail to allow the licensee to determine the precise nature of the work being invoiced.

Response. As stated in the past, the NRC believes that sufficient information is provided on the invoices for licensees and applicants to base payment of the costs assessed under part 170. The NRC has specific policies and procedures in place for NRC staff to follow when recording time in the Human Resources Management System (HRMS), the agency's current system for tracking staff hours expended. The system contains specific codes for the various types of licensing reviews, leave, training, general administration effort, *etc.* From HRMS, the fee billing system captures the NRC staff hours for activities billable under part 170 as well as work effort code descriptions for those billable hours. For these activities, the staff hours, work effort codes, the initials of the staff member performing the work, and the date the work performed or completed are printed on the enclosure to the part 170 invoices. Additionally, the inspection report number is provided on inspection fee bills. The work effort codes are the only available data describing the work performed, and they are the lowest level of detail available in HRMS. Thus, the NRC believes that the summary work descriptions shown on the invoices are sufficient to allow licensees to identify the subject of the NRC's efforts.

For contractor costs billed to uranium recovery licensees under part 170, the NRC includes copies of the contractor's summary cost reports with the invoices. Upon specific request, the NRC will send all available information in support of the bill to any licensee or applicant who does not understand the charges or needs more information in order to understand the bill. This has always been an option available to licensees and applicants who feel they need more information on the costs billed.

When practicable the NRC has improved the invoicing process. For example, as announced in the March 17, 2011, proposed rule, the NRC has started billing the licensee for any inspection cost incurred during the quarter, even if the inspection is ongoing. Billing for incurred inspection costs began in the first quarter of FY 2011, when the NRC's new accounting system was implemented. Comments on previous fee rulemakings and the instant rulemaking have supported this change.

B. Specific Part 171 Issues

1. Changing NRC's Small Entity Size Standards

Comment. One commenter stated the annual fees are already excessive for a small healthcare entity and continue to increase. The commenter suggested that the NRC should consider changing the small entity definition so small healthcare entities that have less than 100 employees and a small portion of their activities related to nuclear isotopes can qualify for the small entity fees. The commenter further suggested that the gross-receipts requirement should only include the gross-receipts related to a nuclear activity or that the small business category be based on the number of employees rather than receipts.

Response. The NRC has considered comments in previous fee rulemakings that the fees for small businesses be based on various factors such as the number of gauges used, the volume of patients administered to, or receipts from the use of regulated activities. The NRC has consistently rejected these alternatives because they would not necessarily meet the goal of the Regulatory Flexibility Act (RFA) to minimize the impact of agency actions on small entities. For example, a large medical establishment would pay a reduced fee if only a small part of its business involved nuclear procedures, whereas a small medical facility whose entire business involves nuclear procedures would pay a larger fee. Basing the fees on the small entity size standards ensures that the benefits of reduced fees apply only to small entities. The NRC's receipts-based size standard for small business not engaged in manufacturing is based on the most commonly used Small Business Administration (SBA) size standard.

The NRC also notes that the purpose of this rule is to amend the fees charged to its applicants and licensees. The size standards used to qualify an NRC licensee as a ''small entity'' under the RFA are codified in 10 CFR 2.810. Thus, they are beyond the scope of this rule and the commenter's suggestion that the size standards be revised is not being addressed in this final rule. However, the commenter may submit a Petition for Rulemaking to revise the size standards under 10 CFR 2.810. Instructions for submitting a petition can be found at *http://www.nrc.gov/about-nrc/regulatory/rulemaking/petition-rule.html.*

2. Fee-Relief Activities

Comment. One commenter representing the commercial nuclear energy industry proposed that NRC implement a process of distinguishing between the fee recovery and fee-relief sources of funds so that the user fee is not used as an additional source of funding for appropriated programs or vice versa. The commenter further stated that this would demonstrate that the budget fairly reflects those activities that are licensee-specific. The commenter also proposed that NRC identify the budget resources that will be used to review the impacts of the event at the Fukushima Daiichi plant in Japan upon U.S. power reactors as a fee-relief activity.

Response. In response to the commenter's recommendation to distinguish between fee recovery and fee-relief sources, OBRA-90 requires that NRC recover approximately 90 percent of its budget authority from fees that are based on a fair and equitable distribution of costs to its licensees. As part of the annual fee rule process, the NRC determines which costs do not directly benefit current licensees and therefore should be included as fee-relief activities. Several factors, including the current fiscal year budgeted activities, existing law, Commission policy, and the type and number of NRC licenses are used in determining how the budgeted resources are allocated to the various fee-relief activities. The NRC believes the existing methodology for determining fee-relief activities and applying any shortfall or surplus is reasonable and fair. Any changes to the format or structure of the NRC budget submission to OMB are outside the scope of this rulemaking and will not be discussed in this rule.

In response to the commenter's proposal that budget resources used to

review the impacts of the event at the Fukushima Daiichi plant upon U.S. power plants be allocated as fee-relief, the NRC resources used to develop lessons learned from the event in Japan benefit the U.S. regulatory program and are considered within the fee base. NRC's resources used to support Japan and the U.S. Embassy in Japan are included in the International fee-relief activity. Therefore, the NRC is retaining the budget allocation as outlined in the proposed rule.

3. Fuel Facilities

Comment. One commenter requested that the proposed ''Scrap/Waste'' effort factor for a hot cell facility licensed under fee category 1A(2)(c) be corrected from a moderate to a low level of effort and the annual fee be adjusted accordingly. The commenter asserted that as the only license in this category, the generation of scrap and waste is low for activities in the hot cell facility under Vallecitos license SNM–960 and thus requires a low level effort for NRC safety oversight.

Response. In each category of the annual fee determination, the staff bases its assessment on the authorized activities under the license. A licensee's operations may not be at the maximum level authorized by the license. SNM–960 (Special Nuclear Materials license) is unique in that the Vallecitos facility has commercial spent (irradiated) fuel. The hazards related to this type of SNM and the potential for waste generated by it require a greater level of regulatory and safety oversight. Therefore, the NRC is retaining the effort/fee determination matrix as outlined in the proposed rule.

Comment. The commenter also requested that the NRC consider whether some portion of the budgeted resources for the regulatory framework for reprocessing be spread over other fee classes where the licensees could benefit from a reprocessing facility.

Response. In accordance with OBRA-90, to the maximum extent practicable, the agency's budget is allocated to the fee classes that the budgeted activities support. As the commenter stated, the NRC is considering establishing the framework for licensing a reprocessing facility as a fuel facility. Thus, the NRC determined the budgeted resources for the regulatory framework activity support the fuel facility fee class. The commenter did not provide sufficient information to the NRC to warrant a change to the budget allocation for this activity. Therefore, the NRC is retaining the budget allocation as outlined in the proposed rule.

4. Agreement State Activities

Comment. Some commenters expressed concern about the impact on NRC licensees once additional states become Agreement States.

Response. This concern has been largely addressed by legislation. To address fairness and equity concerns associated with licensees paying for the cost of activities that do not directly benefit them, the FY 2001 Energy and Water Development Appropriations Act amended OBRA-90 to decrease the NRC's fee recovery amount to 90 percent beginning in FY 2005. In response to concerns about the declining number of NRC licensees as more states become Agreement States, the NRC notes that the fee calculation methodology considers the percentage of licensees in Agreement States in establishing fees for the materials users fee class. As explained in the proposed fee rule, the budgeted resources providing support to Agreement States or their licensees are included in total fee-relief costs, which are offset by the 10 percent non-fee recoverable funding (fee relief) provided by Congress. For example, if the NRC develops a rule, guidance document, or a tracking system that is associated with or otherwise benefits Agreement State licensees, the costs of these activities are prorated to the fee-relief activities according to the percentage of licensees in that fee class in Agreement States (*e.g.,* if 85 percent of materials users licensees are in Agreement States, 85 percent of these regulatory infrastructure costs are included in the fee-relief category). To the extent that the 10 percent fee relief is insufficient to cover the total cost of all fee-relief activities, these remaining costs are spread to all licensees based on their percentage of the budget.

C. Other Issues

1. Proposed Fee Rule Supporting Information

Comment. One commenter stated that the proposed fee rule did not adequately explain the basis for the Uranium Mill Tailings Radiation Control Act (UMTRCA) Title I budgeted costs. This commenter requests that the NRC provide site-specific budget details in the final rule and supporting documents so the associated NRC fee can be appropriately budgeted and allocated internally. The commenter notes that no detail is provided in the working papers associated with the proposed rule to support the increase in FTE allocation for UMTRCA Title I budgeted costs.

Response. The NRC acknowledges the importance of site-specific information for the commenter's internal needs. However, the annual fees are established to recover the difference between the NRC's total recoverable budgeted costs and the estimated part 170 collections. Thus, the annual fees are not site-specific but represent the budgeted resources supporting generic regulatory effort for the fee class. In response to the comment on the detail provided in the work papers, the purpose of this rulemaking is to describe and then solicit and evaluate comments on the allocation of the NRC's budget for fee calculation purposes. The rule and supporting work papers are not intended to justify why the budgeted resources for a given budget activity increased. The allocation of the budget to each fee class and fee-relief category was included in the work papers supporting the proposed rule. The work papers show the total budgeted FTE and contract costs at the product line for each activity. The work papers also provide additional information for some classes of licensees, such as uranium recovery, when additional allocation and calculation detail is required to ensure that the fees are fair and equitable to all licensees within the class. Additionally, the contact listed in the proposed fee rule was available during the public comment period to answer any questions that commenters had on the development of the proposed fees. Therefore, the NRC believes that ample information was available on which to base constructive comments on the proposed revisions to parts 170 and 171.

2. International Activities Supporting Recovery in Japan

Comment. One commenter representing the commercial nuclear energy industry requested that the NRC seek input from industry stakeholders to the extent that expected licensing actions are impacted, if resources originally designated for domestic activities are ultimately diverted to international activities. In addition, the commenter suggests that if additional funds are needed to support the event at the Fukushima Daiichi plant in Japan, the NRC should request additional appropriation from Congress, rather than imposing an additional surcharge to the industry through the user fee.

Response. The NRC acknowledges the industry stakeholders' concerns regarding possible delays to licensing actions. Nonetheless, the responsibility for work schedules regarding NRC licensing activities is not within the scope of this rulemaking. Therefore the work schedules are not addressed in this final rule, but are being addressed

by the project manager's communication with licensees. In response to the commenter's statement on NRC's appropriation, as stated in an earlier response, the NRC resources used to develop lessons learned from the event in Japan benefit the U.S. regulatory program and are considered within the fee base. The NRC resources used to support Japan are included in the International fee-relief activity. NRC's budget requests to Congress are not within the scope of this rulemaking. Therefore, this final rule does not address the commenter's suggestion regarding the NRC's funding needs.

III. Final Action

The NRC is amending its licensing, inspection, and annual fees to recover approximately 90 percent of its FY 2011 budget authority less the appropriations for non-fee items. The NRC's total budget authority for FY 2011 is $1,054.1 million. The non-fee items include $10 million appropriated from the NWF, $0.5 million for WIR activities, and $26 million for generic homeland security activities. Based on the 90 percent fee-recovery requirement, the NRC will have to recover approximately $915.8 million in FY 2011 through part 170 licensing and inspection fees and part 171 annual fees. The amount required by law to be recovered through fees for FY 2011 is $3.6 million more than the amount estimated for recovery in FY 2010, an increase of less than 1 percent.

The FY 2011 fee recovery amount is increased by $0.4 million to account for billing adjustments (*i.e.,* for FY 2011 invoices that the NRC estimates will not be paid during the fiscal year, less payments received in FY 2011 for prior year invoices). This leaves approximately $916.2 million to be billed as fees in FY 2011 through part 170 licensing and inspection fees and part 171 annual fees.

Table I summarizes the budget and fee recovery amounts for FY 2011. FY 2010 amounts are provided for comparison purposes. (Individual values may not sum to totals due to rounding.)

TABLE I—BUDGET AND FEE RECOVERY AMOUNTS

[Dollars in millions]

	FY 2010 final rule	FY 2011 final rule
Total Budget Authority	$1,066.9	$1,054.1
Less Non-Fee Items	*− 53.3*	*− 36.5*
Balance	$1,013.6	$1,017.6
Fee Recovery Rate for FY 2011	*90%*	*90%*
Total Amount to be Recovered for FY 2011	$912.2	$915.8
Part 171 Billing Adjustments:		
Unpaid Current Year Invoices (estimated)	2.1	3.0
Less Payments Received in Current Year for Previous Year Invoices (estimated)	*− 3.2*	*− 2.6*
Subtotal	− 1.1	0.4
Amount to be Recovered Through Parts 170 and 171 Fees	$911.1	$916.2
Less Estimated Part 170 Fees	*− 357.3*	*− 369.3*
Part 171 Fee Collections Required	$553.8	$546.9

In this final rule, as compared to the proposed rule, NRC amends fees for power reactors, non-power reactors, uranium recovery facilities, most fuel facilities, some small materials users, and DOE's transportation license. The changes to the annual fees are due to the small increase in the NRC's appropriation as compared to the President's budget amount used in the proposed rule. The appropriation increase resulted in a small increase to the average FTE rate that is used to calculate the budget allocation to each of the fee classes and fee-relief activities in the final rule. Also, this final rule includes an adjustment in the calculation for the materials users' annual fees to reflect the deletion of fee category 3.D. In addition, this final rule includes a revision to the descriptions of Import and Export fee categories 15.F. and 15.J. The revision is described in Section III.A.2., ''Flat'' Application Fee Changes, of this document.

The NRC estimates that $369.3 million will be recovered from part 170 fees in FY 2011, which is unchanged from the proposed rule estimate. This represents an increase of approximately 1.5 percent as compared to the actual part 170 collections of $364 million for FY 2010. The NRC derived the FY 2011 estimate of part 170 fee collections based on the latest billing data available for each license fee class, with adjustments to account for changes in the NRC's FY 2011 budget, as appropriate. The remaining $546.9 million is to be recovered through the part 171 annual fees in FY 2011, which is an increase of less than 1 percent compared to actual part 171 collections of $545.6 million for FY 2010. The change for each class of licensees affected is discussed in Section III.B.3. below.

The FY 2011 final fee rule is a ''major rule'' as defined by the Congressional Review Act of 1996 (5 U.S.C. 801–808). Therefore, the NRC's fee schedules for FY 2011 will become effective 60 days after publication of the final rule in the **Federal Register**. The NRC will send an invoice for the amount of the annual fee to reactor licensees, 10 CFR part 72 licensees, major fuel cycle facilities, and other licensees with annual fees of $100,000 or more, upon publication of the FY 2011 final rule. For these licensees, payment is due on the effective date of the FY 2011 final rule. Because these licensees are billed quarterly, the payment due is the amount of the total FY 2011 annual fee, less payments made in the first three quarters of the fiscal year.

Materials licensees with annual fees of less than $100,000 are billed annually. Those materials licensees whose license anniversary date during

FY 2011 falls before the effective date of the FY 2011 final rule will be billed for the annual fee during the anniversary month of the license at the FY 2010 annual fee rate. Those materials licensees whose license anniversary date falls on or after the effective date of the FY 2011 final rule will be billed for the annual fee at the FY 2011 annual fee rate during the anniversary month of the license, and payment will be due on the date of the invoice.

The NRC currently does not mail the final fee rule to all licensees, but will send the final rule to any licensee or other person upon specific request. To request a copy, contact the License Fee Billing Help Desk, Accounts Receivable/Payable Branch, Division of the Controller, Office of the Chief Financial Officer, at 301–415–7554, or e-mail *fees.resource@nrc.gov.* In addition to publication in the **Federal Register**, the final rule will be available on the Internet at *http://www.regulations.gov.*

The NRC, in conjunction with internal and external stakeholders, reviewed its fee policies for power reactors in anticipation of the receipt of new applications for licensing small and medium sized commercial nuclear reactors. The NRC has prepared a paper for the Commission's information in support of the Nuclear Energy Institute's position to calculate annual fees for each new licensed power reactor as a function of its licensed thermal power rating (MWt).

The NRC changed its policy with regard to billing inspection costs, as discussed in the FY 2010 final rule (75 FR 34220, 34223; June 16, 2010). Instead of billing a licensee when the inspection is completed, the NRC now bills the licensee for any inspection cost incurred during the quarter even if the inspection is ongoing. Billing for incurred inspection costs began in the first quarter of FY 2011, when the NRC's new accounting system was implemented. This policy change did not require a revision to part 170.

The NRC is amending 10 CFR parts 170 and 171 as follows:

A. Amendments to 10 CFR Part 170: Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, As Amended

In FY 2011, the NRC is increasing the hourly rate to recover the full cost of activities under part 170, and using this rate to calculate ''flat'' application fees.

The NRC is making the following changes:

1. Hourly Rate

The NRC's hourly rate is used in assessing full cost fees for specific services provided, as well as flat fees for certain application reviews. The NRC is changing the FY 2011 hourly rate to $273. This rate would be applicable to all activities for which fees are assessed under §§ 170.21 and 170.31.

The FY 2011 hourly rate is higher than the FY 2010 hourly rate of $259. The increase in hourly rate is due to higher FY 2011 agency overhead budgeted resources, and a small reduction in the number of direct full-time equivalents (FTEs). In FY 2011 the NRC revised its budget structure. This new structure allows the agency to accurately identify all its direct and overhead costs. Under this new FY 2011 structure, more of the budgeted resources have been identified as overhead costs. The agency is using this information to further streamline its costs and make efficient use of all its resources. The FTEs for direct program activities in the Reactor program decrease in FY 2011. The hourly rate calculation is described in further detail in the following paragraphs.

The NRC's hourly rate is derived by dividing the sum of recoverable budgeted resources for (1) mission direct program salaries and benefits; (2) mission indirect program support; and (3) agency corporate support and the Inspector General (IG), by mission direct FTE hours. The mission direct FTE hours are the product of the mission direct FTE times the hours per direct FTE. The only budgeted resources excluded from the hourly rate are those for contract activities related to mission direct and fee-relief activities.

In FY 2011, the NRC is using 1,371 hours per direct FTE, the same amount as FY 2010, to calculate the hourly fees. The NRC has reviewed data from its time and labor system to determine if the annual direct hours worked per direct FTE estimate requires updating for the FY 2011 fee rule. Based on this review of the most recent data available, the NRC determined that 1,371 hours is the best estimate of direct hours worked annually per direct FTE. This estimate excludes all indirect activities such as training, general administration, and leave.

Table II shows the results of the hourly rate calculation methodology. FY 2010 amounts are provided for comparison purposes. (Individual values may not sum to totals due to rounding.)

TABLE II—HOURLY RATE CALCULATION

	FY 2010 final rule	FY 2011 final rule
Mission Direct Program Salaries & Benefits	$343.8	$337.4
Mission Indirect Program Support	135.6	25.9
Agency Corporate Support, and the IG	*330.4*	*474.1*
Subtotal	809.8	837.4
Less Offsetting Receipts	*−0.0*	*−0.0*
Total Budget Included in Hourly Rate	809.8	837.4
Mission Direct FTEs	2,276	2,236
Professional Hourly Rate (Total Budget Included in Hourly Rate divided by Mission Direct FTE Hours)	259	273

As shown in Table II, dividing the FY 2011 $837.4 million budget amount included in the hourly rate by total mission direct FTE hours (2,236 FTE times 1,371 hours) results in an hourly rate of $273. The hourly rate is rounded to the nearest whole dollar.

2. ''Flat'' Application Fee Changes

The NRC is adjusting the current flat application fees in § 170.21 and 170.31 to reflect the revised hourly rate of $273. These flat fees are calculated by multiplying the average professional staff hours needed to process the licensing actions by the final professional hourly rate for FY 2011.

Biennially, the NRC evaluates historical professional staff hours used to process a new license application for materials users fee categories subject to flat application fees. This is in

accordance with the requirements of the Chief Financial Officer's Act. The NRC conducted this biennial review for the FY 2011 fee rule which also included license and amendment applications for import and export licenses.

Evaluation of the historical data for the FY 2011 fee rule showed that the average number of professional staff hours required to complete licensing actions in the materials program should be increased in some fee categories and decreased in others to more accurately reflect current data for completing these licensing actions. The average number of professional staff hours needed to complete new licensing actions was last updated for the FY 2009 final fee rule. Thus, the revised final average professional staff hours in this fee rule reflect the changes in the NRC licensing review program that have occurred since that time.

The higher hourly rate of $273 is the main reason for the increases in the application fees. Application fees for 10 fee categories (3.G., 3.I., 3.P., 3.R.1., 3.R.2., 4.B., 7.C., 8.A., 9.C., and 9.D. under § 170.31) also increase because of the results of the biennial review, which showed an increase in average time to process these types of license applications. The decrease in fees for 9 fee categories (2.C., 3.B., 3.H., 3.L., 3.M., 3.O., 5.A., 7.A., and 9.A. under § 170.31) is due to a decrease in average time to process these types of applications.

The flat application fee for fee Category 17., Master materials licenses of broad scope issued to Government agencies, is being eliminated. Instead, any application received for fee Category 17. will be reviewed on a full-cost basis; *i.e.,* staff hours required to review application times the NRC hourly rate. The regulatory effort to review a new master materials license application varies with each license application. Therefore, a full cost application fee would be equitable since the actual cost of review will be charged to the applicant.

Based on the biennial review, the following changes have been made to the fee categories for import and export licenses. The current export fee Category 15.H. is deleted because the description for the fee was incorrect and not used in export licensing. The current fee Category 15.I. is renumbered as 15.H. A new export fee Category 15.I. is established to reflect a new fee category for government-to-government consents for exports of Category 1 quantities for radioactive material listed in Appendix P to 10 CFR part 110. The new 15.I. fee category reflects the NRC's activity related to obtaining government-to-government consents as specified in § 110.42(e)(3). In addition, fee categories 15.M. through and including 15.Q. are being eliminated since the requirement to obtain a specific license for imports of radioactive materials listed in Appendix P to 10 CFR part 110 was eliminated as part of a 2010 rule change to 10 CFR part 110 (75 FR 44072; July 28, 2010). Also, the descriptions for fee categories 15.F. and 15.J. are revised to replace the reference to § 110.42(e)(4) with § 110.40(b)(6)(i) that was added to 10 CFR part 110 as part of the 2010 rule change to clarify the requirement for Commission level review.

The amounts of the materials licensing flat fees are rounded so that the fees would be convenient to the user and the effects of rounding would be minimal. Fees under $1,000 are rounded to the nearest $10, fees that are greater than $1,000 but less than $100,000 are rounded to the nearest $100, and fees that are greater than $100,000 are rounded to the nearest $1,000.

The licensing flat fees are applicable for fee categories K.1. through K.5. of § 170.21, and fee categories 1.C., 1.D., 2.B., 2.C., 3.A. through 3.S., 4.B. through 9.D., 10.B., 15.A. through 15.L., 15.R. and 16. of § 170.31. Applications filed on or after the effective date of the FY 2011 final fee rule are subject to the revised fees in the final rule.

In FY 2011, NRC will be eliminating fee Category 3.D. under byproduct materials since the agency does not expect to receive any license under the current definition of this fee category. The fee category will be reserved for future use.

3. Administrative Amendments

In § 170.11, the NRC is inserting a semicolon at the end of paragraph (a)(1)(iii)(A), inserting a semicolon and the word ''and'' at the end of paragraph (a)(1)(iii)(B), and removing and reserving paragraph (a)(1)(iii)(D) for ease of reading. There is no change to the NRC's fee exemption policy.

In § 170.31, the NRC is eliminating footnote 5 and renumbering footnote 6 to 5.

In summary, the NRC is making the following changes to 10 CFR part 170:

1. Establish a revised professional hourly rate to use in assessing fees for specific services;

2. Revise the license application fees to reflect the FY 2011 hourly rate and the results of the biennial review of average professional staff hours; revise the fee categories for import and export licenses; eliminate fee category 3.D; and change the application fee from a flat rate to full cost for fee Category 17; and

3. Make certain administrative changes for purposes of improving the clarity of the rule.

B. Amendments to 10 CFR Part 171: Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC

The NRC will use its fee-relief surplus by decreasing all licensees' annual fees based on their percentage share of the fee recoverable budget authority. This rulemaking also makes changes to the number of NRC licensees and to establish rebaselined annual fees based on Public Law 112–10. The amendments are described as follows:

1. Application of Fee-Relief and Low-Level Waste (LLW) Surcharge

The NRC will use its fee-relief surplus by decreasing all licensees' annual fees, based on their percentage share of the budget. The NRC applies the 10 percent of its budget that is excluded from fee recovery under OBRA–90, as amended (fee-relief), to offset the total budget allocated for activities which do not directly benefit current NRC licensees. The budget for these fee-relief activities is totaled and then reduced by the amount of the NRC's fee-relief. Any difference between the fee-relief and the budgeted amount of these activities results in a fee-relief adjustment (increase or decrease) to all licensees' annual fees, based on their percentage share of the budget, which is consistent with the existing fee methodology.

The FY 2011 budgeted resources for NRC's fee-relief activities are $95.4 million. The NRC's 10 percent fee-relief amount in FY 2011 is $101.8 million, leaving a $6.4 million fee-relief surplus that will reduce all licensees' annual fees based on their percentage share of the budget. The FY 2011 budget for fee-relief activities is lower than FY 2010, primarily due to a decrease in budgeted resources for nonprofit educational exemptions, international activities, small entity subsidies, and grants for fellowships and scholarships. These values are shown in Table III. The FY 2010 amounts are provided for comparison purposes. (Individual values may not sum to totals due to rounding.)

TABLE III—FEE-RELIEF ACTIVITIES

[Dollars in millions]

Fee-relief activities	FY 2010 Budgeted costs	FY 2011 Budgeted costs
1. Activities not attributable to an existing NRC licensee or class of licensee:		
a. International activities	18.2	15.1
b. Agreement State oversight	11.2	14.1
c. Scholarships and Fellowships	15.0	11.5
2. Activities not assessed part 170 licensing and inspection fees or part 171 annual fees based on existing law or Commission policy:		
a. Fee exemption for nonprofit educational institutions	17.4	13.3
b. Costs not recovered from small entities under 10 CFR 171.16(c)	6.1	5.6
c. Regulatory support to Agreement States	23.1	18.0
d. Generic decommissioning/reclamation (not related to the power reactor and spent fuel storage fee classes)	15.1	16.6
e. In situ leach rulemaking and unregistered general licensees	*2.4*	*1.2*
Total fee-relief activities	108.5	95.4
Less 10 percent of NRC's FY 2011 total budget (less non-fee items)	*− 101.4*	*− 101.8*
Fee-Relief Adjustment to be Allocated to All Licensees' Annual Fees	$7.1	−6.4

Table IV shows how the NRC is allocating the $6.4 million fee-relief surplus adjustment to each license fee class. As explained previously, the NRC is allocating this fee-relief adjustment to each license fee class based on the percent of the budget for that fee class compared to the NRC's total budget. The fee-relief surplus adjustment is subtracted from the required annual fee recovery from each fee class.

Separately, the NRC has continued to allocate the LLW surcharge based on the volume of LLW disposal of three classes of licenses: Operating reactors, fuel facilities, and materials users. Because LLW activities support NRC licensees, the costs of these activities are recovered through annual fees. In FY 2011, this allocation percentage was updated based on review of recent data which reflects the change in the support to the various fee classes. The allocation percentage of LLW surcharge increased for operating reactors and fuel facilities, and decreased for materials users compared to FY 2010.

Table IV also shows the allocation of the LLW surcharge activity. For FY 2011, the total budget allocated for LLW activity is $3.0 million. (Individual values may not sum to totals due to rounding.)

TABLE IV—ALLOCATION OF FEE-RELIEF ADJUSTMENT AND LLW SURCHARGE, FY 2011

[Dollars in millions]

	LLW surcharge		Fee-relief adjustment		Total
	Percent	$	Percent	$	$
Operating Power Reactors	70.0	2.1	85.9	−5.5	−3.4
Spent Fuel Storage/Reactor Decommissioning	–	–	3.7	−0.2	−0.2
Research and Test Reactors	–	–	0.2	0.0	0.0
Fuel Facilities	24.0	0.7	6.2	−0.4	0.3
Materials Users	6.0	0.2	2.8	−0.2	0.0
Transportation	–	–	0.5	0.0	0.0
Uranium Recovery	–	–	*0.8*	*0.0*	*0.0*
Total	100.0	3.0	100.0	−6.4	−3.3

2. Revised Annual Fees

The NRC is revising its annual fees in §§ 171.15 and 171.16 for FY 2011 to recover approximately 90 percent of the NRC's FY 2011 budget authority, after subtracting the non-fee amounts and the estimated amount to be recovered through part 170 fees. The part 170 collections estimate for this final rule ($369.3) increases by $12 million from the FY 2010 fee rule. The total amount to be recovered through annual fees for this final rule is $546.9 million, which is a $0.5 million increase from the proposed rule. The required annual fee collection in FY 2010 was $553.8 million.

The Commission has determined (71 FR 30721; May 30, 2006) that the agency should proceed with a presumption in favor of rebaselining when calculating annual fees each year. Under this method, the NRC's budget is analyzed in detail, and budgeted resources are allocated to fee classes and categories of licensees. The Commission expects that most years there will be budgetary and other changes that warrant the use of the rebaselining method.

As compared with FY 2010 annual fees, the FY 2011 final rebaselined fees are higher for four classes of licensees (spent fuel storage and reactors in decommissioning facilities, research and test reactors, fuel facilities and transportation), and lower for one class of licensees (power reactors). Within the uranium recovery fee class, the annual fees for most licensees decrease, while the annual fee for one fee category increases. The annual fee increases for most fee categories in the materials users' fee class.

The NRC's total fee recoverable budget, as mandated by law, is approximately $3.6 million higher in FY 2011 as compared with FY 2010. The FY 2011 budget was allocated to the fee classes that the budgeted activities support. The increase is primarily due to the higher FY 2011 budget supporting the spent fuel storage and transportation activities, fuel facility reviews, materials users' activities, uranium recovery facilities, and research and test reactor reviews.

The factors affecting all annual fees include the distribution of budgeted costs to the different classes of licenses (based on the specific activities the NRC will perform in FY 2011), the estimated part 170 collections for the various classes of licenses, and allocation of the fee-relief surplus adjustment to all fee classes. The percentage of the NRC's budget not subject to fee recovery remained at 10 percent from FY 2010 to FY 2011.

Table V shows the rebaselined fees for FY 2011 for a representative list of categories of licensees. The FY 2010 amounts are provided for comparison purposes. (Individual values may not sum to totals due to rounding.)

TABLE V—REBASELINED ANNUAL FEES

Class/category of licenses	FY 2010 Annual fee	FY 2011 Annual fee
Operating Power Reactors (Including Spent Fuel Storage/Reactor Decommissioning Annual Fee)	$4,784,000	$4,673,000
Spent Fuel Storage/Reactor Decommissioning	148,000	241,000
Research and Test Reactors (Nonpower Reactors)	81,700	86,300
High Enriched Uranium Fuel Facility	5,439,000	6,085,000
Low Enriched Uranium Fuel Facility	2,047,000	2,290,000
UF_6 Conversion Facility	1,111,000	1,243,000
Conventional Mills	38,300	32,300
Typical Materials Users:		
Radiographers (Category 3O)	28,200	25,700
Well Loggers (Category 5A)	11,900	10,000
Gauge Users (Category 3P)	4,500	4,800
Broad Scope Medical (Category 7B)	45,100	45,400

The work papers that support this final rule show in detail the allocation of NRC's budgeted resources for each class of licenses and how the fees are calculated. Beginning in FY 2011, the NRC transitioned to a new budget structure. Therefore, the reports included in these work papers summarize the FY 2011 budgeted FTE and contract dollars allocated to each fee class and fee-relief category at the product line level. Since the FY 2010 and FY 2011 budget structures are appreciably different, the reports comparing the FY 2011 allocations to FY 2010 are at a higher summary level. The work papers are available online at *http://www.regulations.gov* by searching on Docket ID NRC–2011–0016 and in the NRC Library (ML11147A057) *http://www.nrc.gov/reading-rm/adams.html.* The work papers may also be examined at the NRC PDR located at One White Flint North, Room O–1F22, 11555 Rockville Pike, Rockville, Maryland 20852.

The budgeted costs allocated to each class of licenses and the calculations of the rebaselined fees are described in paragraphs a. through h. of this section. Individual values in the Tables presented in this section may not sum to totals due to rounding.

a. Fuel Facilities

The FY 2011 budgeted costs to be recovered in the annual fees assessment to the fuel facility class of licenses [which includes licensees in fee categories 1.A.(1)(a), 1.A.(1)(b), 1.A.(2)(a), 1.A.(2)(b), 1.A.(2)(c), 1.E., and 2.A.(1), under § 171.16] is approximately $30.1 million. This value is based on the full cost of budgeted resources associated with all activities that support this fee class, which is reduced by estimated part 170 collections and adjusted for allocated generic transportation resources and fee-relief. In FY 2011, the LLW surcharge for fuel facilities is added to the allocated fee-relief adjustment (see Table IV in Section III.B.1., ''Application of Fee-Relief and Low-Level Waste Surcharge'' of this document). The summary calculations used to derive this value are presented in Table VI for FY 2011, with FY 2010 values shown for comparison. (Individual values may not sum to totals due to rounding.)

TABLE VI—ANNUAL FEE SUMMARY CALCULATIONS FOR FUEL FACILITIES

[Dollars in millions]

Summary fee calculations	FY 2010 Final	FY 2011 Final
Total budgeted resources	$48.8	$55.7
Less estimated part 170 receipts	*− 21.2*	*− 26.6*
Net part 171 resources	27.6	29.1
Allocated generic transportation	+ 0.5	+ 0.6
Fee-relief adjustment/LLW surcharge	+ 0.7	+ 0.3
Billing adjustments	*− 0.1*	*− 0.0*
Total required annual fee recovery	28.8	30.1

The increase in total budgeted resources allocated to this fee class from FY 2010 to FY 2011 is primarily due to increased support for licensing amendments, and rulemaking for regulatory framework for reprocessing.

In the final rule, due to the final appropriation adjustment, the FY 2011 annual fee for all but one fuel facility fee category increased slightly from the proposed rule.

The total required annual fee recovery amount is allocated to the individual fuel facility licensees, based on the effort/fee determination matrix developed for the FY 1999 final fee rule (64 FR 31447; June 10, 1999). In the matrix included in the publicly available NRC work papers, licensees are grouped into categories according to their licensed activities (*i.e.,* nuclear material enrichment, processing operations, and material form) and the level, scope, depth of coverage, and rigor of generic regulatory programmatic effort applicable to each category from a safety and safeguards perspective. This methodology can be applied to determine fees for new licensees, current licensees, licensees in unique license situations, and certificate holders.

This methodology is adaptable to changes in the number of licensees or certificate holders, licensed or certified material and/or activities, and total programmatic resources to be recovered through annual fees. When a license or certificate is modified, it may result in a change of category for a particular fuel facility licensee, as a result of the methodology used in the fuel facility effort/fee matrix. Consequently, this change may also have an effect on the fees assessed to other fuel facility licensees and certificate holders. For example, if a fuel facility licensee amends its license/certificate (*e.g.,* decommissioning or license termination) that results in it not being subject to part 171 costs applicable to the fee class, then the budgeted costs for the safety and/or safeguards components will be spread among the remaining fuel facility licensees/ certificate holders.

The methodology is applied as follows. First, a fee category is assigned, based on the nuclear material and activity authorized by license or certificate. Although a licensee/ certificate holder may elect not to fully use a license/certificate, the license/ certificate is still used as the source for determining authorized nuclear material possession and use/activity. Second, the category and license/certificate information are used to determine where the licensee/certificate holder fits into the matrix. The matrix depicts the categorization of licensees/certificate holders by authorized material types and use/activities.

Each year, the NRC's fuel facility project managers and regulatory analysts determine the level of effort associated with regulating each of these facilities. This is done by assigning, for each fuel facility, separate effort factors for the safety and safeguards activities associated with each type of regulatory activity. The matrix includes ten types of regulatory activities, including enrichment and scrap/waste-related activities (see the work papers for the complete list). Effort factors are assigned as follows: One (low regulatory effort), five (moderate regulatory effort), and ten (high regulatory effort). These effort factors are then totaled for each fee category, so that each fee category has a total effort factor for safety activities and a total effort factor for safeguards activities.

The effort factors for the various fuel facility fee categories are summarized in Table VII. The value of the effort factors shown, as well as the percent of the total effort factor for all fuel facilities, reflects the total regulatory effort for each fee category (not per facility). The following factors have changed compared to FY 2010. The total effort factors for the Limited Operations fee category has increased from FY 2010, while the Uranium Enrichment fee category factors decreased from FY 2010 primarily due to a shift of one licensee from the Uranium Enrichment fee category to Limited Operations fee category.

TABLE VII—EFFORT FACTORS FOR FUEL FACILITIES, FY 2011

Facility type (fee category)	Number of facilities	Effort factors (percent of total)	
		Safety	Safeguards
High Enriched Uranium Fuel (1.A.(1)(a))	2	89 (35.5)	97 (46.2)
Low Enriched Uranium Fuel (1.A.(1)(b))	3	70 (27.9)	35 (16.7)
Limited Operations (1.A.(2)(a))	2	15 (6.0)	8 (3.8)
Gas Centrifuge Enrichment Demonstration (1.A.(2)(b))	1	3 (1.2)	15 (7.1)
Hot Cell (1.A.(2)(c))	1	6 (2.4)	3 (1.4)
Uranium Enrichment (1.E)	2	56 (22.3)	45 (21.4)
UF_6 Conversion (2.A.(1))	1	12 (4.8)	7 (3.3)

For FY 2011, the total budgeted resources for safety activities, before the fee-relief adjustment is made, are $16,234,471. This amount is allocated to each fee category based on its percent of the total regulatory effort for safety activities. For example, if the total effort factor for safety activities for all fuel facilities is 100, and the total effort factor for safety activities for a given fee category is 10, that fee category will be allocated 10 percent of the total budgeted resources for safety activities. Similarly, the budgeted resources amount of $13,517,946 for safeguards activities is allocated to each fee category based on its percent of the total regulatory effort for safeguards activities. The fuel facility fee class' portion of the fee-relief adjustment ($343,140) is allocated to each fee category based on its percent of the total regulatory effort for both safety and safeguards activities. The annual fee per licensee is then calculated by dividing the total allocated budgeted resources for the fee category by the number of licensees in that fee category. The fee (rounded) for each facility is summarized in Table VIII.

TABLE VIII—ANNUAL FEES FOR FUEL FACILITIES

Facility type (fee category)	FY 2011 Final annual fee
High Enriched Uranium Fuel (1.A.(1)(a))	$6,085,000
Low Enriched Uranium Fuel (1.A.(1)(b))	2,290,000

TABLE VIII—ANNUAL FEES FOR FUEL FACILITIES—Continued

Facility type (fee category)	FY 2011 Final annual fee
Limited Operations Facility (1.A.(2)(a))	752,000
Gas Centrifuge Enrichment Demonstration (1.A.(2)(b))	1,178,000
Hot Cell (and others) (1.A.(2)(c))	589,000
Uranium Enrichment (1.E.)	3,271,000
UF_6 Conversion (2.A.(1))	1,243,000

b. Uranium Recovery Facilities

The total FY 2011 budgeted costs to be recovered through annual fees assessed to the uranium recovery class [which includes licensees in fee categories 2.A.(2)(a), 2.A.(2)(b), 2.A.(2)(c), 2.A.(2)(d), 2.A.(2)(e), 2.A.(3), 2.A.(4), 2.A.(5) and 18.B., under § 171.16], is approximately $1.0 million. The derivation of this value is shown in Table IX, with FY 2010 values shown for comparison purposes.

TABLE IX—ANNUAL FEE SUMMARY CALCULATIONS FOR URANIUM RECOVERY FACILITIES

[Dollars in millions]

Summary fee calculations	FY 2010 Final	FY 2011 Final
Total budgeted resources	$6.69	$7.15
Less estimated part 170 receipts	*− 5.83*	*− 6.09*
Net part 171 resources	0.86	1.06
Allocated generic transportation	N/A	N/A
Fee-relief adjustment	+ 0.05	− 0.05
Billing adjustments	*− 0.01*	*0.00*
Total required annual fee recovery	0.91	1.01

The increase in total budgeted resources allocated to this fee class from FY 2010 to FY 2011 is primarily due to an increase in DOE Title I licensing activities partially offset by an increase in part 170 estimates. In the final rule, due to the final appropriation adjustment, the FY 2011 annual fee for all uranium recovery fee categories increased slightly from the proposed rule.

Since FY 2002, the NRC has computed the annual fee for the uranium recovery fee class by allocating the total annual fee amount for this fee class between the DOE and the other licensees in this fee class. The NRC regulates DOE's Title I and Title II activities under the Uranium Mill Tailings Radiation Control Act (UMTRCA). The Congress established the two programs, Title I and Title II under UMTRCA, to protect the public and the environment from uranium milling. The UMTRCA Title I program is for remedial action at abandoned mill tailings sites where tailings resulted largely from production of uranium for the weapons program. The NRC also regulates DOE's UMTRCA Title II program which is directed toward uranium mill sites licensed by the NRC or Agreement States in or after 1978.

In FY 2011, the annual fee assessed to DOE includes recovery of the costs specifically budgeted for NRC's Title I activities, plus 10 percent of the remaining annual fee amount, including the fee-relief and generic/other costs, for the uranium recovery class. The remaining 90 percent of the fee-relief and generic/other costs are assessed to the other NRC licensees in this fee class that are subject to annual fees. The distribution of 10 percent of the generic budgeted costs to DOE and 90 percent to other facilities is a change from FY 2010 when the distribution was 35 percent and 65 percent to DOE and other facilities, respectively. The change reflects NRC's current level of effort.

The costs to be recovered through annual fees assessed to the uranium recovery class are shown in Table X.

TABLE X—COSTS RECOVERED THROUGH ANNUAL FEES; URANIUM RECOVERY FEE CLASS

DOE Annual Fee Amount (UMTRCA Title I and Title II) general licenses:	
UMTRCA Title I budgeted costs less part 170 receipts	$745,889
10 percent of generic/other uranium recovery budgeted costs	31,312
10 percent of uranium recovery fee-relief adjustment	*− 4,992*
Total Annual Fee Amount for DOE (rounded)	772,000
Annual Fee Amount for Other Uranium Recovery Licenses:	
90 percent of generic/other uranium recovery budgeted costs less the amounts specifically budgeted for Title I activities	281,810
90 percent of uranium recovery fee-relief adjustment	*− 44,924*
Total Annual Fee Amount for Other Uranium Recovery Licenses	236,887

The DOE fee increases in FY 2011 compared to FY 2010 due to higher budgeted resources for UMTRCA Title I activities. The annual fee for other uranium recovery licensees decreases in FY 2011. Although the distribution percentage of the generic budgeted costs to other uranium facilities increased from FY 2010, the total annual fee

amount to be recovered decreases in FY 2011 compared to FY 2010, primarily due to increased activities for DOE Title I facilities.

The NRC will continue to use a matrix (which is included in the supporting work papers) to determine the level of effort associated with conducting the generic regulatory actions for the different (non-DOE) licensees in this fee class. The weights derived in this matrix are used to allocate the approximately $237,000 annual fee amount to these licensees. The use of this uranium recovery annual fee matrix was established in the FY 1995 final fee rule (60 FR 32217; June 20, 1995). The FY 2011 matrix is described as follows.

First, the methodology identifies the categories of licenses included in this fee class (besides DOE). In FY 2011, these categories are conventional uranium mills and heap leach facilities, uranium solution mining and resin In Situ Recovery (ISR) facilities, mill tailings disposal facilities (11e.(2) disposal facilities), and uranium water treatment facilities.

Second, the matrix identifies the types of operating activities that support and benefit these licensees. The activities related to generic decommissioning/reclamation are not included in the matrix, because they are included in the fee-relief activities. Therefore, they are not a factor in determining annual fees. The activities included in the FY 2011 matrix are operations, waste operations, and groundwater protection. The relative weight of each type of activity is then determined, based on the regulatory resources associated with each activity. The operations, waste operations, and groundwater protection activities have weights of 0, 5, and 10, respectively, in the FY 2011 matrix.

Each year, the NRC determines the level of benefit to each licensee for generic uranium recovery program activities for each type of generic activity in the matrix. This is done by assigning, for each fee category, separate benefit factors for each type of regulatory activity in the matrix. Benefit factors are assigned on a scale of 0 to 10 as follows: Zero (no regulatory benefit), five (moderate regulatory benefit), and ten (high regulatory benefit). These benefit factors are first multiplied by the relative weight assigned to each activity (described previously). Total benefit factors by fee category, and per licensee in each fee category, are then calculated. These benefit factors thus reflect the relative regulatory benefit associated with each licensee and fee category.

The benefit factors per licensee and per fee category, for each of the non-DOE fee categories included in the uranium recovery fee class, are as follows:

TABLE XI—BENEFIT FACTORS FOR URANIUM RECOVERY LICENSES

Fee category	Number of licensees	Benefit factor per licensee	Total value	Benefit factor percent total
Conventional and Heap Leach mills (2.(A).2.a.)	1	200	200	14
Basic In Situ Recovery facilities (2.(A).2.b.)	4	190	760	52
Expanded In Situ Recovery facilities (2.(A).2.c.)	1	215	215	15
In Situ Recovery Resin Facilities (2.(A).2.d.)	1	180	180	12
11e.(2) disposal incidental to existing tailings sites (2.(A).4.)	1	65	65	4
Uranium water treatment (2.(A).5.)	1	45	45	3
			1,465	

Applying these factors to the approximately $237,000 in budgeted costs to be recovered from non-DOE uranium recovery licensees results in the total annual fees for each fee category. The annual fee per licensee is calculated by dividing the total allocated budgeted resources for the fee category by the number of licensees in that fee category, as summarized in Table XII:

TABLE XII—ANNUAL FEES FOR URANIUM RECOVERY LICENSEES

[Other than DOE]

Facility type (fee category)	FY 2011 Final annual fee
Conventional and Heap Leach mills (2.A.(2)(a))	$32,300
Basic In Situ Recovery facilities (2.A.(2)(b))	30,700
Expanded In Situ Recovery facilities (2.A.(2)(c))	34,800
In Situ Recovery Resin facilities (2.A.(2)(d))	29,100
11e.(2) disposal incidental to existing tailings sites (2.A.(4))	10,500
Uranium water treatment (2.A.(5))	7,300

c. Operating Power Reactors

The $460.9 million in budgeted costs to be recovered through FY 2011 annual fees assessed to the power reactor class was calculated as shown in Table XIII. The FY 2010 values are shown for comparison. (Individual values may not sum to totals due to rounding.)

TABLE XIII—ANNUAL FEE SUMMARY CALCULATIONS FOR OPERATING POWER REACTORS

[Dollars in millions]

Summary fee calculations	FY 2010 Final	FY 2011 Final
Total budgeted resources	$787.3	$783.6

TABLE XIII—ANNUAL FEE SUMMARY CALCULATIONS FOR OPERATING POWER REACTORS—Continued

[Dollars in millions]

Summary fee calculations	FY 2010 Final	FY 2011 Final
Less estimated part 170 receipts	*−312.5*	*−320.6*
Net part 171 resources	474.8	463.0
Allocated generic transportation	+ 0.8	+ 0.9
Fee-relief adjustment/LLW surcharge	+7.5	−3.4
Billing adjustments	*−1.0*	*0.4*
Total required annual fee recovery	482.1	460.9

The annual fee for power reactors decreases in FY 2011 compared to FY 2010 due to a decrease in budgeted resources, increase in the part 170 collections estimate, and the fee-relief surplus adjustment. The budgeted costs to be recovered through annual fees to power reactors are divided equally among the 104 power reactors licensed to operate resulting in a FY 2011 annual fee of $4,432,000 per reactor. Additionally, each power reactor licensed to operate would be assessed the FY 2011 spent fuel storage/reactor decommissioning annual fee of $241,000. The total FY 2011 annual fee is $4,673,000 for each power reactor licensed to operate. In the final rule, due to the final appropriation adjustment, the FY 2011 annual fee for power reactors increased slightly from the proposed rule. The annual fees for power reactors are presented in § 171.15.

d. Spent Fuel Storage/Reactors in Decommissioning

For FY 2011, budgeted costs of approximately $29.7 million for spent fuel storage/reactor decommissioning are to be recovered through annual fees assessed to 10 CFR part 50 power reactors, and to part 72 licensees who do not hold a part 50 license. Those reactor licensees that have ceased operations and have no fuel onsite are not subject to these annual fees. Table XIV shows the calculation of this annual fee amount. The FY 2010 values are shown for comparison. (Individual values may not sum to totals due to rounding.)

TABLE XIV—ANNUAL FEE SUMMARY CALCULATIONS FOR THE SPENT FUEL STORAGE/REACTOR IN DECOMMISSIONING FEE CLASS

[Dollars in millions]

Summary fee calculations	FY 2010 Final	FY 2011 Final
Total budgeted resources	$24.1	$33.4
Less estimated part 170 receipts	*−6.4*	*−4.0*
Net part 171 resources	17.7	29.4
Allocated generic transportation	+0.4	+0.5
Fee-relief adjustment	+0.2	−0.2
Billing adjustments	*0.0*	*0.0*
Total required annual fee recovery	18.2	29.7

The value of total budgeted resources for this fee class is higher in FY 2011 than in FY 2010, due to increased budgeted resources for spent fuel storage licensing and certification activities and lower part 170 collections estimate, partially offset by the fee-relief surplus adjustment. The required annual fee recovery amount is divided equally among 123 licensees, resulting in a FY 2011 annual fee of $241,000 per licensee, which is unchanged from the proposed rule.

e. Research and Test Reactors (Nonpower Reactors)

Approximately $350,000 in budgeted costs is to be recovered through annual fees assessed to the research and test reactor class of licenses for FY 2011. Table XV summarizes the annual fee calculation for research and test reactors for FY 2011. The FY 2010 values are shown for comparison. (Individual values may not sum to totals due to rounding.)

TABLE XV—ANNUAL FEE SUMMARY CALCULATIONS FOR RESEARCH AND TEST REACTORS

[Dollars in millions]

Summary fee calculations	FY 2010 Final	FY 2011 Final
Total budgeted resources	$1.31	$1.87
Less estimated part 170 receipts	*−1.01*	*−1.54*
Net part 171 resources	0.30	0.33
Allocated generic transportation	+0.01	+0.02
Fee-relief adjustment	+0.01	−0.01
Billing adjustments	*0.00*	*0.00*

TABLE XV—ANNUAL FEE SUMMARY CALCULATIONS FOR RESEARCH AND TEST REACTORS—Continued

[Dollars in millions]

Summary fee calculations	FY 2010 Final	FY 2011 Final
Total required annual fee recovery	0.33	0.35

The increase in annual fees from FY 2010 to FY 2011 is primarily due to an increase in budgeted costs for review of licensing amendments partially offset by higher estimated part 170 revenue and the fee-relief surplus adjustment. The required annual fee recovery amount is divided equally among the four research and test reactors subject to annual fees and results in an FY 2011 annual fee of $86,300 for each licensee. In the final rule, due to the final appropriation adjustment, the FY 2011 annual fee for non-power reactors increased slightly from the proposed rule.

f. Rare Earth Facilities

The agency does not anticipate receiving an application for a rare earth facility this fiscal year, so no budgeted resources are allocated to this fee class, and no annual fee will be published in FY 2011.

g. Materials Users

Table XVI shows the calculation of the FY 2011 annual fee amount for materials users licensees. The FY 2010 values are shown for comparison. Note the following fee categories under § 171.16 are included in this fee class: 1.C., 1.D., 2.B., 2.C., 3.A. through 3.S., 4.A. through 4.C., 5.A., 5.B., 6.A., 7.A. through 7.C., 8.A., 9.A. through 9.D., 16, and 17. (Individual values may not sum to totals due to rounding.)

TABLE XVI—ANNUAL FEE SUMMARY CALCULATIONS FOR MATERIALS USERS

[Dollars in millions]

Summary fee calculations	FY 2010 Final	FY 2011 Final
Total budgeted resources	$28.8	$30.0
Less estimated part 170 receipts	*− 1.8*	*− 1.6*
Net part 171 resources	27.0	28.5
Allocated generic transportation	+0.8	+1.0
Fee-relief adjustment/LLW surcharge	+0.9	−0.0
Billing adjustments	*− 0.0*	*− 0.0*
Total required annual fee recovery	28.7	29.5

The total required annual fees to be recovered from materials licensees increase in FY 2011, mainly because of increases in the budgeted resources allocated to this fee class for licensing and oversight activities, and lower estimated part 170 fee revenue compared to FY 2010. Annual fees for most fee categories within the materials users' fee class increase while some decrease due to a decrease in inspection costs in certain fee categories. In the final rule, due to the final appropriation adjustment, the FY 2011 annual fee for some fee categories increased slightly from the proposed rule. Also in the final rule, the fees for some fee categories have decreased from the proposed rule due to a fee calculation adjustment. In the proposed rule fee category 3.D., which the NRC is eliminating in FY 2011, was inadvertently included in the annual fee calculation for the materials users' fee class. An adjustment in this final rule removes fee category 3.D. from the fee calculation, resulting in a slight decrease in fees from the proposed rule for some fee categories.

To equitably and fairly allocate the $29.5 million in FY 2011 budgeted costs to be recovered in annual fees assessed to the approximately 3,000 diverse materials users licensees, the NRC will continue to base the annual fees for each fee category within this class on the part 170 application fees and estimated inspection costs for each fee category. Because the application fees and inspection costs are indicative of the complexity of the license, this approach continues to provide a proxy for allocating the generic and other regulatory costs to the diverse categories of licenses based on the NRC's cost to regulate each category. This fee calculation also continues to consider the inspection frequency (priority), which is indicative of the safety risk and resulting regulatory costs associated with the categories of licenses.

The annual fee for these categories of materials users licenses is developed as follows:

Annual fee = Constant × [Application Fee + (Average Inspection Cost divided by Inspection Priority)] + Inspection Multiplier × (Average Inspection Cost divided by Inspection Priority) + Unique Category Costs.

The constant is the multiple necessary to recover approximately $21.2 million in general costs (including allocated generic transportation costs) and is 1.53 for FY 2011. The average inspection cost is the average inspection hours for each fee category multiplied by the hourly rate of $273. The inspection priority is the interval between routine inspections, expressed in years. The inspection multiplier is the multiple necessary to recover approximately $8.2 million in inspection costs, and is 2.3 for FY 2011. The unique category costs are any special costs that the NRC has budgeted for a specific category of licenses. For FY 2011, approximately $113,600 in budgeted costs for the implementation of revised 10 CFR part 35, Medical Use of Byproduct Material (unique costs), has been allocated to holders of NRC human-use licenses.

The annual fee to be assessed to each licensee also includes a share of the fee-relief surplus adjustment of approximately $178,000 allocated to the materials users fee class (see Section III.B.1., ''Application of Fee-Relief and Low-Level Waste Surcharge,'' of this document), and for certain categories of these licensees, a share of the approximately $189,000 in LLW surcharge costs allocated to the fee class. The annual fee for each fee category is shown in § 171.16(d).

In FY 2011, the NRC is eliminating fee Category 3.D. under byproduct materials since the agency does not expect to receive any license under the current definition of this fee category. The fee category will be reserved for future use.

h. Transportation

Table XVII shows the calculation of the FY 2011 generic transportation budgeted resources to be recovered through annual fees. The FY 2010 values are shown for comparison. (Individual values may not sum to totals due to rounding.)

TABLE XVII—ANNUAL FEE SUMMARY CALCULATIONS FOR TRANSPORTATION

[Dollars in millions]

Summary fee calculations	FY 2010 Final	FY 2011 Final
Total budgeted resources	$6.6	$7.5
Less estimated part 170 receipts	*– 3.3*	*– $3.4*
Net part 171 resources	3.3	4.1

The NRC must approve any package used for shipping nuclear material before shipment. If the package meets NRC requirements, the NRC issues a Radioactive Material Package Certificate of Compliance (CoC) to the organization requesting approval of a package. Organizations are authorized to ship radioactive material in a package approved for use under the general licensing provisions of 10 CFR part 71. The resources associated with generic transportation activities are distributed to the license fee classes based on the number of CoCs benefitting (used by) that fee class, as a proxy for the generic transportation resources expended for each fee class.

The total FY 2011 budgeted resources for generic transportation activities, including those to support DOE CoCs, are $4.1million. The increase in part 171 resources in FY 2011 compared to FY 2010 is primarily due to an increase in budgeted resources for transportation regulatory programs. The net part 171 resources for these activities in the FY 2011 final rule increased slightly from the proposed rule due to the final appropriation adjustment. Generic transportation resources associated with fee-exempt entities are not included in this total. These costs are included in the appropriate fee-relief category (*e.g.,* the fee-relief category for nonprofit educational institutions).

Consistent with the policy established in the NRC's FY 2006 final fee rule (71 FR 30721; May 30, 2006), the NRC will recover generic transportation costs unrelated to DOE as part of existing annual fees for license fee classes. The NRC will continue to assess a separate annual fee under § 171.16, fee Category 18.A., for DOE transportation activities. The amount of the allocated generic resources is calculated by multiplying the percentage of total CoCs used by each fee class (and DOE) by the total generic transportation resources to be recovered.

The distribution of these resources to the license fee classes and DOE is shown in Table XVIII. The distribution is adjusted to account for the licensees in each fee class that are fee-exempt. For example, if 3 CoCs benefit the entire research and test reactor class, but only 4 of 32 research and test reactors are subject to annual fees, the number of CoCs used to determine the proportion of generic transportation resources allocated to research and test reactor annual fees equals ((4/32)*3), or 0.4 CoCs.

TABLE XVIII—DISTRIBUTION OF GENERIC TRANSPORTATION RESOURCES, FY 2011

[Dollars in millions]

License fee class/DOE	Number CoCs benefiting fee class or DOE	Percentage of total CoCs	Allocated generic transportation resources
Total	85.5	100.0	$4.11
DOE	22.0	25.7	1.06
Operating Power Reactors	19.0	22.2	0.91
Spent Fuel Storage/Reactor Decommissioning	10.0	11.7	0.48
Research and Test Reactors	0.5	0.6	0.02
Fuel Facilities	13.0	15.2	0.63
Materials Users	21.0	24.6	1.01

The NRC will continue to assess an annual fee to DOE based on the part 71 CoCs it holds and not allocate these DOE-related resources to other licensees' annual fees, because these resources specifically support DOE. Note that DOE's annual fee includes a reduction for the fee-relief surplus adjustment (see Section III.B.1, ''Application of Fee-Relief and Low-Level Waste Surcharge,'' of this document), resulting in a total annual fee of $1,030,000 for FY 2011. This fee increase from FY 2010 is primarily related to higher budgeted resources for the NRC's transportation activities. The FY 2011 final rule amount for DOE increased by $2,000 compared to the proposed rule due to the final appropriation adjustment.

3. Small Entity Fees

The small entity annual fee is charged to those licensees who qualify as small entities and who would otherwise be required to pay annual fees as stipulated under § 171.16(d). In FY 2011, the NRC reexamined the small entity fee, including the new methodology developed in FY 2009. Per the methodology, the upper-tier small entity fee amount was 74% higher than the current fee of $1,900, a reflection of the increase in annual fees for the materials users licensees for the past 2 years. Implementing this increase would have a disproportionate impact upon NRC's small entity licensees. Therefore, in FY 2011, the NRC is limiting the increase

for upper tier fees to $2,300, a 21 percent increase, and the lower tier fees to $500, a 25 percent increase.

4. Administrative Amendments

Eliminate fee Category 3.D. in § 171.16 since the agency currently does not have any licensee under this category. Based on the definition of this fee category no future licensees are expected since there are no nonprofit educational institutions that are distributors of radiopharmaceuticals.

In summary, the NRC is—

1. Using the NRC's fee-relief surplus to reduce all licensees' annual fees, based on their percentage share of the NRC budget;

2. Establishing rebaselined annual fees for FY 2011;

3. Increasing the maximum small entity fee from $1,900 to $2,300, and the lower tier fee from $400 to $500;

4. Eliminating fee Category 3.D.

IV. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 3701) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies, unless using these standards is inconsistent with applicable law or is otherwise impractical. The NRC is amending the licensing, inspection, and annual fees charged to its licensees and applicants as necessary to recover approximately 90 percent of its budget authority in FY 2011, as required by the OBRA–90, as amended. This action does not constitute the establishment of a standard that contains generally applicable requirements.

V. Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental assessment nor an environmental impact statement has been prepared for the final rule. By its very nature, this regulatory action does not affect the environment and, therefore, no environmental justice issues are raised.

VI. Paperwork Reduction Act Statement

This final rule does not contain information collection requirements and, therefore, is not subject to the requirements of 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 for information or an information collection requirement, unless the requesting document displays a currently valid Office of Management and Budget control number.

VII. Regulatory Analysis

With respect to 10 CFR part 170, this final rule was developed under Title V of the IOAA (31 U.S.C. 9701) and the Commission's fee guidelines. When developing these guidelines, the Commission took into account guidance provided by the U.S. Supreme Court on March 4, 1974, in *National Cable Television Association, Inc.* v. *United States,* 415 U.S. 36 (1974) and *Federal Power Commission* v. *New England Power Company,* 415 U.S. 345 (1974). In these decisions, the Court held that the IOAA authorizes an agency to charge fees for special benefits rendered to identifiable persons measured by the ''value to the recipient'' of the agency service. The meaning of the IOAA was further clarified on December 16, 1976, by four decisions of the U.S. Court of Appeals for the District of Columbia: *National Cable Television Association* v. *Federal Communications Commission,* 554 F.2d 1094 (DC Cir. 1976); *National Association of Broadcasters* v. *Federal Communications Commission,* 554 F.2d 1118 (DC Cir. 1976); *Electronic Industries Association* v. *Federal Communications Commission,* 554 F.2d 1109 (DC Cir. 1976); and *Capital Cities Communication, Inc.* v. *Federal Communications Commission,* 554 F.2d 1135 (DC Cir. 1976). The Commission's fee guidelines were developed based on these legal decisions.

The Commission's fee guidelines were upheld on August 24, 1979, by the U.S. Court of Appeals for the Fifth Circuit in *Mississippi Power and Light Co.* v. *U.S. Nuclear Regulatory Commission,* 601 F.2d 223 (5th Cir. 1979), *cert. denied,* 444 U.S. 1102 (1980). This court held that—

(1) The NRC had the authority to recover the full cost of providing services to identifiable beneficiaries;

(2) The NRC could properly assess a fee for the costs of providing routine inspections necessary to ensure a licensee's compliance with the Atomic Energy Act of 1954, as amended, and with applicable regulations;

(3) The NRC could charge for costs incurred in conducting environmental reviews required by the National Environmental Policy Act (42 U.S.C. 4321);

(4) The NRC properly included the costs of uncontested hearings and of administrative and technical support services in the fee schedule;

(5) The NRC could assess a fee for renewing a license to operate a low-level radioactive waste burial site; and

(6) The NRC's fees were not arbitrary or capricious.

With respect to 10 CFR part 171, on November 5, 1990, the Congress passed OBRA–90, which required that, for FYs 1991 through 1995, approximately 100 percent of the NRC budget authority, less appropriations from the NWF, be recovered through the assessment of fees. The OBRA–90 was subsequently amended to extend the 100 percent fee recovery requirement through FY 2000. The FY 2001 Energy and Water Development Appropriation Act (EWDAA) amended OBRA–90 to decrease the NRC's fee recovery amount by 2 percent per year beginning in FY 2001, until the fee recovery amount was 90 percent in FY 2005. The FY 2006 EWDAA extended this 90 percent fee recovery requirement for FY 2006. Section 637 of the Energy Policy Act of 2005 made the 90 percent fee recovery requirement permanent in FY 2007. As a result, the NRC is required to recover approximately 90 percent of its FY 2011 budget authority, less the amounts appropriated from the NWF, WIR, and generic homeland security activities through fees. To comply with this statutory requirement and in accordance with § 171.13, the NRC is publishing the amount of the FY 2011 annual fees for reactor licensees, fuel cycle licensees, materials licensees, and holders of CoCs, registrations of sealed source and devices, and Government agencies. The OBRA–90, consistent with the accompanying Conference Committee Report, and the amendments to OBRA–90, provides that—

(1) The annual fees will be based on approximately 90 percent of the Commission's FY 2011 budget of $1,054.1 million not including the following items: Funds appropriated from the NWF to cover the NRC's high-level waste program, amounts appropriated for WIR and generic homeland security activities, and the amount of funds collected from part 170 fees;

(2) The annual fees shall, to the maximum extent practicable, have a reasonable relationship to the cost of regulatory services provided by the Commission; and

(3) The annual fees be assessed to those licensees the Commission, in its discretion, determines can fairly, equitably, and practicably contribute to their payment.

Part 171, which established annual fees for operating power reactors, effective October 20, 1986 (51 FR 33224; September 18, 1986), was challenged and upheld in its entirety in *Florida Power and Light Company* v. *United States,* 846 F.2d 765 (DC Cir. 1988), *cert. denied,* 490 U.S. 1045 (1989). Further, the NRC's FY 1991 annual fee rule methodology was upheld by the DC Circuit Court of Appeals in *Allied Signal* v. *NRC,* 988 F.2d 146 (DC Cir. 1993).

VIII. Regulatory Flexibility Analysis

The NRC is required by the OBRA–90, as amended, to recover approximately 90 percent of its FY 2011 budget authority through the assessment of user fees. This Act further requires that the NRC establish a schedule of charges that fairly and equitably allocates the aggregate amount of these charges among licensees.

This final rule establishes the schedules of fees that are necessary to implement the Congressional mandate for FY 2011. This final rule results in increases in the annual fees charged to certain licensees and holders of certificates, registrations, and approvals, and in decreases in annual fees charged to others. Licensees affected by the annual fee increases and decreases include those that qualify as a small entity under NRC's size standards in 10 CFR 2.810. The Regulatory Flexibility Analysis, prepared in accordance with 5 U.S.C. 604, is included as Appendix A to this final rule.

The Small Business Regulatory Enforcement Fairness Act (SBREFA) requires all Federal agencies to prepare a written compliance guide for each rule for which the agency is required by 5 U.S.C. 604 to prepare a regulatory flexibility analysis. Therefore, in compliance with the law, Attachment 1 of Appendix A to the Regulatory Flexibility Analysis is the small entity compliance guide for FY 2011.

IX. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this final rule and that a backfit analysis is not required for this final rule. The backfit analysis is not required because these amendments do not require the modification of, or additions to, systems, structures, components, or the design of a facility, or the design approval or manufacturing license for a facility, or the procedures or organization required to design, construct, or operate a facility.

X. Congressional Review Act

In accordance with the Congressional Review Act of 1996 (5 U.S.C. 801–808), the NRC has determined that this action is a major rule and has verified the determination with the Office of Information and Regulatory Affairs of the Office of Management and Budget.

List of Subjects

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Byproduct material, Holders of certificates, Registrations, Approvals, Intergovernmental relations, Non-payment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 170 and 171.

PART 170—FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

■ 1. The authority citation for part 170 continues to read as follows:

Authority: Section 9701, Pub. L. 97–258, 96 Stat. 1051 (31 U.S.C. 9701); sec. 301, Pub. L. 92–314, 86 Stat. 227 (42 U.S.C. 2201w); sec. 201, Pub. L. 93–438, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 205a, Pub. L. 101–576, 104 Stat. 2842, as amended (31 U.S.C. 901, 902); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note), sec. 623, Pub. L. 109–58, 119 Stat. 783 (42 U.S.C. 2201(w)); sec. 651(e), Pub. L.109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

■ 2. In § 170.11, paragraph (a)(1)(iii)(D) is removed and reserved and paragraphs (a)(1)(iii)(A) and (a)(1)(iii)(B) are revised to read as follows:

§ 170.11 Exemptions.

(a)(1)(iii) * * *

(A) The report should be submitted for the specific purpose of supporting ongoing NRC generic regulatory improvements or efforts (*e.g.,* rules, regulations, regulatory guides, and policy statements), and the agency, at the time the document is submitted, plans to use it for that purpose. The exemption applies even if ultimately the NRC does not use the document as planned;

(B) The NRC must be the primary beneficiary of the NRC's review and approval of these documents. This exemption does not apply to a topical report submitted for the purpose of obtaining NRC approval for future use of the report by the industry to address licensing or safety issues, even though the NRC may realize some benefits from its review and approval of the document; and

* * * * *

■ 3. Section 170.20 is revised to read as follows:

§ 170.20 Average cost per professional staff-hour.

Fees for permits, licenses, amendments, renewals, special projects, 10 CFR part 55 re-qualification and replacement examinations and tests, other required reviews, approvals, and inspections under §§ 170.21 and 170.31 will be calculated using the professional staff-hour rate of $273 per hour.

■ 4. In § 170.21, in the table, fee Category K is revised to read as follows:

§ 170.21 Schedule of fees for production and utilization facilities, review of standard referenced design approvals, special projects, inspections, and import and export licenses.

* * * * *

SCHEDULE OF FACILITY FEES

[See footnotes at end of table]

Facility categories and type of fees	Fees [1, 2]
* * * * * * *	
K. Import and export licenses:	
Licenses for the import and export only of production and utilization facilities or the export only of components for production and utilization facilities issued under 10 CFR part 110.	

SCHEDULE OF FACILITY FEES—Continued

[See footnotes at end of table]

Facility categories and type of fees	Fees [1, 2]
1. Application for import or export of production and utilization facilities [4] (including reactors and other facilities) and exports of components requiring Commission and Executive Branch review, for example, actions under 10 CFR 110.40(b).	
Application—new license, or amendment; or license exemption request	$17,800
2. Application for export of reactor and other components requiring Executive Branch review, for example, those actions under 10 CFR 110.41(a).	
Application—new license, or amendment; or license exemption request	9,600
3. Application for export of components requiring the assistance of the Executive Branch to obtain foreign government assurances.	
Application—new license, or amendment; or license exemption request	4,400
4. Application for export of facility components and equipment not requiring Commission or Executive Branch review, or obtaining foreign government assurances.	
Application—new license, or amendment; or license exemption request	2,700
5. Minor amendment of any active export or import license, for example, to extend the expiration date, change domestic information, or make other revisions which do not involve any substantive changes to license terms or conditions or to the type of facility or component authorized for export and therefore, do not require in-depth analysis or review or consultation with the Executive Branch, U.S. host state, or foreign government authorities.	
Minor amendment to license	1,400

[1] Fees will not be charged for orders related to civil penalties or other civil sanctions issued by the Commission under § 2.202 of this chapter or for amendments resulting specifically from the requirements of these orders. For orders unrelated to civil penalties or other civil sanctions, fees will be charged for any resulting licensee-specific activities not otherwise exempted from fees under this chapter. Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under Title 10 of the Code of Federal Regulations (*e.g.,* 10 CFR 50.12, 10 CFR 73.5) and any other sections in effect now or in the future, regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form.

[2] Full cost fees will be determined based on the professional staff time and appropriate contractual support services expended. For applications currently on file and for which fees are determined based on the full cost expended for the review, the professional staff hours expended for the review of the application up to the effective date of the final rule will be determined at the professional rates in effect when the service was provided. For those applications currently on file for which review costs have reached an applicable fee ceiling established by the June 20, 1984, and July 2, 1990, rules, but are still pending completion of the review, the cost incurred after any applicable ceiling was reached through January 29, 1989, will not be billed to the applicant. Any professional staff-hours expended above those ceilings on or after January 30, 1989, will be assessed at the applicable rates established by § 170.20, as appropriate, except for topical reports whose costs exceed $50,000. Costs which exceed $50,000 for any topical report, amendment, revision, or supplement to a topical report completed or under review from January 30, 1989, through August 8, 1991, will not be billed to the applicant. Any professional hours expended on or after August 9, 1991, will be assessed at the applicable rate established in § 170.20.

* * * * *

[4] Imports only of major components for end-use at NRC-licensed reactors are now authorized under NRC general import license.

■ 5. In § 170.31, the table is revised to read as follows:

§ 170.31 Schedule of fees for materials licenses and other regulatory services, including inspections and import and export licenses.

* * * * *

SCHEDULE OF MATERIALS FEES

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2, 3]
1. Special nuclear material:	
A. (1) Licenses for possession and use of U–235 or plutonium for fuel fabrication activities.	
(a) Strategic Special Nuclear Material (High Enriched Uranium) [Program Code(s): 21130]	Full Cost.
(b) Low Enriched Uranium in Dispersible Form Used for Fabrication of Power Reactor Fuel [Program Code(s): 21210]	Full Cost.
(2) All other special nuclear materials licenses not included in Category 1.A.(1) which are licensed for fuel cycle activities.	
(a) Facilities with limited operations [Program Code(s): 21310, 21320]	Full Cost.
(b) Gas centrifuge enrichment demonstration facilities	Full Cost.
(c) Others, including hot cell facilities	Full Cost.
B. Licenses for receipt and storage of spent fuel and reactor-related Greater than Class C (GTCC) waste at an independent spent fuel storage installation (ISFSI) [Program Code(s): 23200].	Full Cost.
C. Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers.[4]	
Application [Program Code(s): 22140]	$1,300.
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity, as defined in § 150.11 of this chapter, for which the licensee shall pay the same fees as those under Category 1.A.[4]	
Application [Program Code(s): 22110, 22111, 22120, 22131, 22136, 22150, 22151, 22161, 22163, 22170, 23100, 23300, 23310].	$2,500.
E. Licenses or certificates for construction and operation of a uranium enrichment facility [Program Code(s): 21200]	Full Cost.
2. Source material:	
A. (1) Licenses for possession and use of source material for refining uranium mill concentrates to uranium hexafluoride [Program Code(s): 11400].	Full Cost.

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2, 3]
(2) Licenses for possession and use of source material in recovery operations such as milling, in-situ recovery, heap-leaching, ore buying stations, ion-exchange facilities, and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	
(a) Conventional and Heap Leach facilities [Program Code(s): 11100]	Full Cost.
(b) Basic In Situ Recovery facilities [Program Code(s): 11500]	Full Cost.
(c) Expanded In Situ Recovery facilities [Program Code(s): 11510]	Full Cost.
(d) In Situ Recovery Resin facilities [Program Code(s): 11550]	Full Cost.
(e) Resin Toll Milling facilities [Program Code(s): 11555]	Full Cost.
(f) Other facilities [Program Code(s): 11700]	Full Cost.
(3) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal, except those licenses subject to the fees in Category 2.A.(2) or Category 2.A.(4) [Program Code(s): 11600, 12000].	Full Cost.
(4) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in Category 2.A.(2) [Program Code(s): 12010].	Full Cost.
(5) Licenses that authorize the possession of source material related to removal of contaminants (source material) from drinking water [Program Code(s): 11820].	Full Cost.
B. Licenses which authorize the possession, use, and/or installation of source material for shielding. Application [Program Code(s): 11210].	$600.
C. All other source material licenses. Application [Program Code(s): 11200, 11220, 11221, 11230, 11300, 11800, 11810]	$5,400.
3. Byproduct material:	
A. Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution.	
Application [Program Code(s): 03211, 03212, 03213]	$12,800.
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution.	
Application [Program Code(s): 03214, 03215, 22135, 22162]	$4,400.
C. Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4).	
Application [Program Code(s): 02500, 02511, 02513]	$6,500.
D. [Reserved]	N/A.[6]
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units).	
Application [Program Code(s): 03510, 03520]	$3,100.
F. Licenses for possession and use of less than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes.	
Application [Program Code(s): 03511]	$6,400.
G. Licenses for possession and use of 10,000 curies or more of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes.	
Application [Program Code(s): 03521]	$61,000.
H. Licenses issued under Subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter. The category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter.	
Application [Program Code(s): 03254, 03255]	$4,300.
I. Licenses issued under Subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter.	
Application [Program Code(s): 03250, 03251, 03252, 03253, 03256]	$11,400.
J. Licenses issued under Subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter.	
Application [Program Code(s): 03240, 03241, 03243]	$2,000.
K. Licenses issued under Subpart B of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter.	
Application [Program Code(s): 03242, 03244]	$1,100.
L. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution.	
Application [Program Code(s): 01100, 01110, 01120, 03610, 03611, 03612, 03613]	$5,400.

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2, 3]
M. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for research and development that do not authorize commercial distribution.	
Application [Program Code(s): 03620]	$3,500.
N. Licenses that authorize services for other licensees, except:	
(1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3.P.; and	
(2) Licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4.A., 4.B., and 4.C.	
Application [Program Code(s): 03219, 03225, 03226]	$6,400.
O. Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations.	
Application [Program Code(s): 03310, 03320]	$4,000.
P. All other specific byproduct material licenses, except those in Categories 4.A. through 9.D.	
Application [Program Code(s): 02400, 02410, 03120, 03121, 03122, 03123, 03124, 03220, 03221, 03222, 03800, 03810, 22130].	$1,500.
Q. Registration of a device(s) generally licensed under part 31 of this chapter.	
Registration	$400.
R. Possession of items or products containing radium-226 identified in 10 CFR 31.12 which exceed the number of items or limits specified in that section.[5]	
1. Possession of quantities exceeding the number of items or limits in 10 CFR 31.12(a)(4), or (5) but less than or equal to 10 times the number of items or limits specified.	
Application [Program Code(s): 02700]	$2,500.
2. Possession of quantities exceeding 10 times the number of items or limits specified in 10 CFR 31.12(a)(4), or (5).	
Application [Program Code(s): 02710]	$1,500.
S. Licenses for production of accelerator-produced radionuclides.	
Application [Program Code(s): 03210]	$6,500.
4. Waste disposal and processing:	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material. [Program Code(s): 03231, 03233, 03235, 03236, 06100, 06101].	Full Cost.
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.	
Application [Program Code(s): 03234]	$8,400.
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.	
Application [Program Code(s): 03232]	$4,900.
5. Well logging:	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies.	
Application [Program Code(s): 03110, 03111, 03112]	$3,300.
B. Licenses for possession and use of byproduct material for field flooding tracer studies.	
Licensing [Program Code(s): 03113]	Full Cost.
6. Nuclear laundries:	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material.	
Application [Program Code(s): 03218]	$21,800.
7. Medical licenses:	
A. Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices.	
Application [Program Code(s): 02300, 02310]	$8,800.
B. Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.	
Application [Program Code(s): 02110]	$8,500.
C. Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices.	
Application [Program Code(s): 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 22160]	$2,700.
8. Civil defense:	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities.	
Application [Program Code(s): 03710]	$2,500.
9. Device, product, or sealed source safety evaluation:	

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2, 3]
A. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution.	
Application—each device	$7,600.
B. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices.	
Application—each device	$8,900.
C. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution.	
Application—each source	$10,300.
D. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel.	
Application—each source	$1,040.
10. Transportation of radioactive material:	
A. Evaluation of casks, packages, and shipping containers.	
1. Spent Fuel, High-Level Waste, and plutonium air packages	Full Cost.
2. Other Casks	Full Cost.
B. Quality assurance program approvals issued under part 71 of this chapter.	
1. Users and Fabricators.	
Application	$3,900.
Inspections	Full Cost.
2. Users.	
Application	$3,900.
Inspections	Full Cost.
C. Evaluation of security plans, route approvals, route surveys, and transportation security devices (including immobilization devices).	Full Cost.
11. Review of standardized spent fuel facilities	Full Cost.
12. Special projects:	
Including approvals, preapplication/licensing activities, and inspections	Full Cost.
13. A. Spent fuel storage cask Certificate of Compliance	Full Cost.
B. Inspections related to storage of spent fuel under § 72.210 of this chapter	Full Cost.
14. A. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities under parts 30, 40, 70, 72, and 76 of this chapter.	Full Cost.
B. Site-specific decommissioning activities associated with unlicensed sites, regardless of whether or not the sites have been previously licensed.	Full Cost.
15. Import and Export licenses:	
Licenses issued under part 110 of this chapter for the import and export only of special nuclear material, source material, tritium and other byproduct material, and the export only of heavy water, or nuclear grade graphite (fee categories 15.A. through 15.E.).	
A. Application for export or import of nuclear materials, including radioactive waste requiring Commission and Executive Branch review, for example, those actions under 10 CFR 110.40(b).	
Application—new license, or amendment; or license exemption request	$17,800.
B. Application for export or import of nuclear material, including radioactive waste, requiring Executive Branch review, but not Commission review. This category includes applications for the export and import of radioactive waste and requires NRC to consult with domestic host state authorities (*i.e.,* Low-Level Radioactive Waste Compact Commission, the U.S. Environmental Protection Agency, *etc.*).	
Application—new license, or amendment; or license exemption request	$9,600.
C. Application for export of nuclear material, for example, routine reloads of low enriched uranium reactor fuel and/or natural uranium source material requiring the assistance of the Executive Branch to obtain foreign government assurances.	
Application—new license, or amendment; or license exemption request	$4,400.
D. Application for export or import of nuclear material, including radioactive waste, not requiring Commission or Executive Branch review, or obtaining foreign government assurances. This category includes applications for export or import of radioactive waste where the NRC has previously authorized the export or import of the same form of waste to or from the same or similar parties located in the same country, requiring only confirmation from the receiving facility and licensing authorities that the shipments may proceed according to previously agreed understandings and procedures.	
Application—new license, or amendment; or license exemption request	$2,700.
E. Minor amendment of any active export or import license, for example, to extend the expiration date, change domestic information, or make other revisions which do not involve any substantive changes to license terms and conditions or to the type/quantity/chemical composition of the material authorized for export and, therefore, do not require in-depth analysis, review, or consultations with other Executive Branch, U.S. host state, or foreign government authorities.	
Minor amendment	$1,400.
Licenses issued under part 110 of this chapter for the import and export only of Category 1 and Category 2 quantities of radioactive material listed in Appendix P to part 110 of this chapter (fee categories 15.F. through 15.R.).	
Category 1 (Appendix P, 10 CFR part 110) Exports:	
F. Application for export of Category 1 materials involving an exceptional circumstances review under 10 CFR 110.40(b)(6)(i).	
Application—new license, or amendment; or license exemption request	$15,000.
G. Application for export of Category 1 materials requiring Executive Branch review, Commission review, and/or government-to-government consent.	
Application—new license, or amendment; or license exemption request	$8,700.

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2, 3]
H. Application for export of Category 1 materials requiring government-to-government consent.	
Application—new license, or amendment; or license exemption request	$5,500.
I. Requests for additional government-to-government consents in support of an export license application or active export license.	
Application—new license, or amendment; or license exemption request	$270.
Category 2 (Appendix P, 10 CFR part 110) Exports:	
J. Application for export of Category 2 materials involving an exceptional circumstances review under 10 CFR 110.40(b)(6)(i).	$15,000.
Application—new license, or amendment; or license exemption request	
K. Applications for export of Category 2 materials requiring Executive Branch review and/or Commission review.	
Application—new license, or amendment; or license exemption request	$8,700.
L. Application for the export of Category 2 materials.	
Application—new license, or amendment; or license exemption request	$5,500.
M. [Reserved]	N/A.[6]
N. [Reserved]	N/A.[6]
O. [Reserved]	N/A.[6]
P. [Reserved]	N/A.[6]
Q. [Reserved]	N/A.[6]
Minor Amendments (Category 1 and 2, Appendix P, 10 CFR part 110, Export and Imports):	
R. Minor amendment of any active export license, for example, to extend the expiration date, change domestic information, or make other revisions which do not involve any substantive changes to license terms and conditions or to the type/quantity/chemical composition of the material authorized for export and, therefore, do not require in-depth analysis, review, or consultations with other Executive Branch, U.S. host state, or foreign authorities.	
Minor amendment	$1,400.
16. Reciprocity:	
Agreement State licensees who conduct activities under the reciprocity provisions of 10 CFR 150.20.	
Application	$2,300.
17. Master materials licenses of broad scope issued to Government agencies.	
Application [Program Code(s): 03614]	Full Cost.
18. Department of Energy.	
A. Certificates of Compliance. Evaluation of casks, packages, and shipping containers (including spent fuel, high-level waste, and other casks, and plutonium air packages).	Full Cost.
B. Uranium Mill Tailings Radiation Control Act (UMTRCA) activities.	Full Cost.

[1] *Types of fees*—Separate charges, as shown in the schedule, will be assessed for preapplication consultations and reviews; applications for new licenses, approvals, or license terminations; possession-only licenses; issuances of new licenses and approvals; certain amendments and renewals to existing licenses and approvals; safety evaluations of sealed sources and devices; generally licensed device registrations; and certain inspections. The following guidelines apply to these charges:

(a) *Application and registration fees.* Applications for new materials licenses and export and import licenses; applications to reinstate expired, terminated, or inactive licenses, except those subject to fees assessed at full costs; applications filed by Agreement State licensees to register under the general license provisions of 10 CFR 150.20; and applications for amendments to materials licenses that would place the license in a higher fee category or add a new fee category must be accompanied by the prescribed application fee for each category.

(1) Applications for licenses covering more than one fee category of special nuclear material or source material must be accompanied by the prescribed application fee for the highest fee category.

(2) Applications for new licenses that cover both byproduct material and special nuclear material in sealed sources for use in gauging devices will pay the appropriate application fee for fee Category 1.C. only.

(b) *Licensing fees.* Fees for reviews of applications for new licenses, renewals, and amendments to existing licenses, preapplication consultations and other documents submitted to the NRC for review, and project manager time for fee categories subject to full cost fees are due upon notification by the Commission in accordance with § 170.12(b).

(c) *Amendment fees.* Applications for amendments to export and import licenses must be accompanied by the prescribed amendment fee for each license affected. An application for an amendment to an export or import license or approval classified in more than one fee category must be accompanied by the prescribed amendment fee for the category affected by the amendment, unless the amendment is applicable to two or more fee categories, in which case the amendment fee for the highest fee category would apply.

(d) *Inspection fees.* Inspections resulting from investigations conducted by the Office of Investigations and nonroutine inspections that result from third-party allegations are not subject to fees. Inspection fees are due upon notification by the Commission in accordance with § 170.12(c).

(e) *Generally licensed device registrations under 10 CFR 31.5.* Submittals of registration information must be accompanied by the prescribed fee.

[2] Fees will not be charged for orders related to civil penalties or other civil sanctions issued by the Commission under 10 CFR 2.202 or for amendments resulting specifically from the requirements of these orders. For orders unrelated to civil penalties or other civil sanctions, fees will be charged for any resulting licensee-specific activities not otherwise exempted from fees under this chapter. Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under Title 10 of the Code of Federal Regulations (*e.g.,* 10 CFR 30.11, 40.14, 70.14, 73.5, and any other sections in effect now or in the future), regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in Categories 9.A. through 9.D.

[3] Full cost fees will be determined based on the professional staff time multiplied by the appropriate professional hourly rate established in § 170.20 in effect when the service is provided, and the appropriate contractual support services expended. For applications currently on file for which review costs have reached an applicable fee ceiling established by the June 20, 1984, and July 2, 1990, rules, but are still pending completion of the review, the cost incurred after any applicable ceiling was reached through January 29, 1989, will not be billed to the applicant. Any professional staff-hours expended above those ceilings on or after January 30, 1989, will be assessed at the applicable rates established by § 170.20, as appropriate, except for topical reports for which costs exceed $50,000. Costs which exceed $50,000 for each topical report, amendment, revision, or supplement to a topical report completed or under review from January 30, 1989, through August 8, 1991, will not be billed to the applicant. Any professional hours expended on or after August 9, 1991, will be assessed at the applicable rate established in § 170.20.

[4] Licensees paying fees under Categories 1.A., 1.B., and 1.E. are not subject to fees under Categories 1.C. and 1.D. for sealed sources authorized in the same license, except for an application that deals only with the sealed sources authorized by the license.

[5] Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. (This exception does not apply if the radium sources are possessed for storage only.)
[6] There are no existing NRC licenses in the fee category.

PART 171—ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

■ 6. The authority citation for part 171 continues to read as follows:

Authority: Section 7601, Pub. L. 99–272, 100 Stat. 146, as amended by sec. 5601, Pub. L. 100–203, 101 Stat. 1330, as amended by sec. 3201, Pub. L. 101–239, 103 Stat. 2132, as amended by sec. 6101, Pub. L. 101–508, 104 Stat. 1388, as amended by sec. 2903a, Pub. L. 102–486, 106 Stat. 3125 (42 U.S.C. 2213, 2214), and as amended by Title IV, Pub. L. 109–103, 119 Stat. 2283 (42 U.S.C. 2214); sec. 301, Pub. L. 92–314, 86 Stat. 227 (42 U.S.C. 2201w); sec. 201, Pub. L. 93–438, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note), sec. 651(e), Pub. L.109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

■ 7. In § 171.15, paragraph (b)(1), the introductory text of paragraph (b)(2), paragraph (c)(1), the introductory text of paragraph (c)(2) and the introductory text of paragraph (d)(1), and paragraphs (d)(2), (d)(3), and paragraph (e), are revised to read as follows:

§ 171.15 Annual fees: Reactor licenses and independent spent fuel storage licenses.

* * * * *

(b)(1) The FY 2011 annual fee for each operating power reactor which must be collected by September 30, 2011, is $4,673,000.

(2) The FY 2011 annual fee is comprised of a base annual fee for power reactors licensed to operate, a base spent fuel storage/reactor decommissioning annual fee, and associated additional charges (fee-relief adjustment). The activities comprising the spent storage/reactor decommissioning base annual fee are shown in paragraphs (c)(2)(i) and (ii) of this section. The activities comprising the FY 2011 fee-relief adjustment are shown in paragraph (d)(1) of this section. The activities comprising the FY 2011 base annual fee for operating power reactors are as follows:

* * * * *

(c)(1) The FY 2011 annual fee for each power reactor holding a 10 CFR part 50 license that is in a decommissioning or possession-only status and has spent fuel onsite, and for each independent spent fuel storage 10 CFR part 72 licensee who does not hold a 10 CFR part 50 license, is $241,000.

(2) The FY 2011 annual fee is comprised of a base spent fuel storage/reactor decommissioning annual fee (which is also included in the operating power reactor annual fee shown in paragraph (b) of this section) and an additional charge (fee-relief adjustment). The activities comprising the FY 2011 fee-relief adjustment are shown in paragraph (d)(1) of this section. The activities comprising the FY 2011 spent fuel storage/reactor decommissioning rebaselined annual fee are:

* * * * *

(d)(1) The fee-relief adjustment allocated to annual fees includes a surcharge for the activities listed in paragraph (d)(1)(i) of this section, plus the amount remaining after total budgeted resources for the activities included in paragraphs (d)(1)(ii) and (d)(1)(iii) of this section are reduced by the appropriations the NRC receives for these types of activities. If the NRC's appropriations for these types of activities are greater than the budgeted resources for the activities included in paragraphs (d)(1)(ii) and (d)(1)(iii) of this section for a given FY, annual fees will be reduced. The activities comprising the FY 2011 fee-relief adjustment are as follows:

* * * * *

(2) The total FY 2011 fee-relief adjustment allocated to the operating power reactor class of licenses is −$3.4 million, not including the amount allocated to the spent fuel storage/reactor decommissioning class. The FY 2011 operating power reactor fee-relief adjustment to be assessed to each operating power reactor is approximately −$32,313. This amount is calculated by dividing the total operating power reactor fee-relief adjustment (−$3.4 million) by the number of operating power reactors (104).

(3) The FY 2011 fee-relief adjustment allocated to the spent fuel storage/reactor decommissioning class of licenses is −$236,916. The FY 2011 spent fuel storage/reactor decommissioning fee-relief adjustment to be assessed to each operating power reactor, each power reactor in decommissioning or possession-only status that has spent fuel onsite, and to each independent spent fuel storage 10 CFR part 72 licensee who does not hold a 10 CFR part 50 license, is approximately −$1,926. This amount is calculated by dividing the total fee-relief adjustment costs allocated to this class by the total number of power reactor licenses, except those that permanently ceased operations and have no fuel onsite, and 10 CFR part 72 licensees who do not hold a 10 CFR part 50 license.

(e) The FY 2011 annual fees for licensees authorized to operate a research and test (nonpower) reactor licensed under part 50 of this chapter, unless the reactor is exempted from fees under § 171.11(a), are as follows:

Research reactor—$86,300.

Test reactor—$86,300.

■ 8. In § 171.16, paragraphs (c) and (d), and the introductory text of paragraph (e) is revised to read as follows:

§ 171.16 Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC.

* * * * *

(c) A licensee who is required to pay an annual fee under this section may qualify as a small entity. If a licensee qualifies as a small entity and provides the Commission with the proper certification along with its annual fee payment, the licensee may pay reduced annual fees as shown in the following table. Failure to file a small entity certification in a timely manner could result in the receipt of a delinquent invoice requesting the outstanding balance due and/or denial of any refund that might otherwise be due. The small entity fees are as follows:

	Maximum annual fee per licensed category
Small Businesses Not Engaged in Manufacturing (Average gross receipts over last 3 completed fiscal years):	

	Maximum annual fee per licensed category
$450,000 to $6.5 million	$2,300
Less than $450,000	500
Small Not-For-Profit Organizations (Annual Gross Receipts):	
$450,000 to $6.5 million	2,300
Less than $450,000	500
Manufacturing entities that have an average of 500 employees or fewer:	
35 to 500 employees	2,300
Fewer than 35 employees	500
Small Governmental Jurisdictions (Including publicly supported educational institutions) (Population):	
20,000 to 50,000	2,300
Fewer than 20,000	500
Educational Institutions that are not State or Publicly Supported, and have 500 Employees or Fewer 35 to 500; employees	2,300
Fewer than 35 employees	500

(d) The FY 2011 annual fees are comprised of a base annual fee and an allocation for fee-relief adjustment. The activities comprising the FY 2011 fee-relief adjustment are shown for convenience in paragraph (e) of this section. The FY 2011 annual fees for materials licensees and holders of certificates, registrations, or approvals subject to fees under this section are shown in the following table:

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC

[See footnotes at end of table]

Category of materials licenses	Annual fees [1, 2, 3]
1. Special nuclear material:	
A. (1) Licenses for possession and use of U–235 or plutonium for fuel fabrication activities.	
(a) Strategic Special Nuclear Material (High Enriched Uranium) [Program Code(s): 21130]	$6,085,000
(b) Low Enriched Uranium in Dispersible Form Used for Fabrication of Power Reactor Fuel [Program Code(s): 21210]	2,290,000
(2) All other special nuclear materials licenses not included in Category 1.A.(1) which are licensed for fuel cycle activities.	
(a) Facilities with limited operations [Program Code(s): 21310, 21320]	752,000
(b) Gas centrifuge enrichment demonstration facilities	1,178,000
(c) Others, including hot cell facilities	589,000
B. Licenses for receipt and storage of spent fuel and reactor-related Greater than Class C (GTCC) waste at an independent spent fuel storage installation (ISFSI) [Program Code(s): 23200]	[11] N/A
C. Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers [Program Code(s): 22140]	3,600
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity, as defined in § 150.11 of this chapter, for which the licensee shall pay the same fees as those for Category 1.A.(2) [Program Code(s): 22110, 22111, 22120, 22131, 22136, 22150, 22151, 22161, 22163, 22170, 23100, 23300, 23310]	6,900
E. Licenses or certificates for the operation of a uranium enrichment facility [Program Code(s): 21200]	3,271,000
2. Source material:	
A. (1) Licenses for possession and use of source material for refining uranium mill concentrates to uranium hexafluoride [Program Code(s): 11400]	1,243,000
(2) Licenses for possession and use of source material in recovery operations such as milling, in-situ recovery, heap-leaching, ore buying stations, ion-exchange facilities and in-processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	
(a) Conventional and Heap Leach facilities [Program Code(s): 11100]	32,300
(b) Basic In Situ Recovery facilities [Program Code(s): 11500]	30,700
(c) Expanded In Situ Recovery facilities [Program Code(s): 11510]	34,800
(d) In Situ Recovery Resin facilities [Program Code(s): 11550]	29,100
(e) Resin Toll Milling facilities [Program Code(s): 11555]	[5] N/A
(f) Other facilities [4] [Program Code(s): 11700]	[5] N/A
(3) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal, except those licenses subject to the fees in Category 2.A.(2) or Category 2.A.(4) [Program Code(s): 11600, 12000]	[5] N/A
(4) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in Category 2.A.(2) [Program Code(s): 12010]	10,500
(5) Licenses that authorize the possession of source material related to removal of contaminants (source material) from drinking water [Program Code(s): 11820]	7,300
B. Licenses that authorize only the possession, use, and/or installation of source material for shielding [Program Code(s): 11210]	1,700
C. All other source material licenses [Program Code(s): 11200, 11220, 11221, 11230, 11300, 11800, 11810]	11,800
3. Byproduct material:	

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1, 2, 3]
A. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution [Program Code(s): 03211, 03212, 03213]	42,500
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution [Program Code(s): 03214, 03215, 22135, 22162]	11,800
C. Licenses issued under §§ 32.72 and/or 32.74 of this chapter authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when included on the same license. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 171.11(a)(1). [Program Code(s): 02500, 02511, 02513]	16,200
D. [Reserved]	[5] N/A
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units) [Program Code(s): 03510, 03520]	8,700
F. Licenses for possession and use of less than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes [Program Code(s): 03511]	15,200
G. Licenses for possession and use of 10,000 curies or more of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes [Program Code(s): 03521]	137,500
H. Licenses issued under Subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter [Program Code(s): 03254, 03255]	8,100
I. Licenses issued under Subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter [Program Code(s): 03250, 03251, 03252, 03253, 03256]	19,600
J. Licenses issued under Subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter [Program Code(s): 03240, 03241, 03243]	4,700
K. Licenses issued under Subpart B of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter [Program Code(s): 03242, 03244]	3,100
L. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution [Program Code(s): 01100, 01110, 01120, 03610, 03611, 03612, 03613]	14,100
M. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for research and development that do not authorize commercial distribution [Program Code(s): 03620]	8,100
N. Licenses that authorize services for other licensees, except: (1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3.P.; and (2) Licenses that authorize waste disposal services are subject to the fees specified in fee categories 4.A., 4.B., and 4.C. [Program Code(s): 03219, 03225, 03226]	14,300
O. Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when authorized on the same license [Program Code(s): 03310, 03320]	25,700
P. All other specific byproduct material licenses, except those in Categories 4.A. through 9.D. [Program Code(s): 02400, 02410, 03120, 03121, 03122, 03123, 03124, 03220, 03221, 03222, 03800, 03810, 22130]	4,800
Q. Registration of devices generally licensed under part 31 of this chapter	[13] N/A
R. Possession of items or products containing radium–226 identified in 10 CFR 31.12 which exceed the number of items or limits specified in that section: [14].	
1. Possession of quantities exceeding the number of items or limits in 10 CFR 31.12(a)(4), or (5) but less than or equal to 10 times the number of items or limits specified [Program Code(s): 02700]	8,900
2. Possession of quantities exceeding 10 times the number of items or limits specified in 10 CFR 31.12(a)(4), or (5) [Program Code(s): 02710]	4,800
S. Licenses for production of accelerator-produced radionuclides [Program Code(s): 03210]	15,200
4. Waste disposal and processing:	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material [Program Code(s): 03231, 03233, 03235, 03236, 06100, 06101]	[5] N/A
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material [Program Code(s): 03234]	31,200

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1, 2, 3]
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material [Program Code(s): 03232]	14,400
5. Well logging:	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies [Program Code(s): 03110, 03111, 03112]	10,000
B. Licenses for possession and use of byproduct material for field flooding tracer studies [Program Code(s): 03113]	[5] N/A
6. Nuclear laundries:	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material [Program Code(s): 03218]	44,800
7. Medical licenses:	
A. Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license [Program Code(s): 02300, 02310]	17,500
B. Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] [Program Code(s): 02110]	45,400
C. Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] [Program Code(s): 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 22160]	8,400
8. Civil defense:	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities [Program Code(s): 03710]	8,900
9. Device, product, or sealed source safety evaluation:	
A. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution	11,500
B. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices	13,500
C. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution	15,600
D. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel	1,600
10. Transportation of radioactive material:	
A. Certificates of Compliance or other package approvals issued for design of casks, packages, and shipping containers.	
1. Spent Fuel, High-Level Waste, and plutonium air packages	[6] N/A
2. Other Casks	[6] N/A
B. Quality assurance program approvals issued under part 71 of this chapter.	
1. Users and Fabricators	[6] N/A
2. Users	[6] N/A
C. Evaluation of security plans, route approvals, route surveys, and transportation security devices (including immobilization devices)	[6] N/A
11. Standardized spent fuel facilities	[6] N/A
12. Special Projects	[6] N/A
13. A. Spent fuel storage cask Certificate of Compliance	[6] N/A
B. General licenses for storage of spent fuel under 10 CFR 72.210	[12] N/A
14. Decommissioning/Reclamation:	
A. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities under parts 30, 40, 70, 72, and 76 of this chapter	[7] N/A
B. Site-specific decommissioning activities associated with unlicensed sites, whether or not the sites have been previously licensed	[7] N/A
15. Import and Export licenses	[8] N/A
16. Reciprocity	[8] N/A
17. Master materials licenses of broad scope issued to Government agencies [Program Code(s): 03614]	476,000
18. Department of Energy:	
A. Certificates of Compliance	[10] 1,030,000

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1, 2, 3]
B. Uranium Mill Tailings Radiation Control Act (UMTRCA) activities	772,000

[1] Annual fees will be assessed based on whether a licensee held a valid license with the NRC authorizing possession and use of radioactive material during the current FY. The annual fee is waived for those materials licenses and holders of certificates, registrations, and approvals who either filed for termination of their licenses or approvals or filed for possession only/storage licenses before October 1, 2010, and permanently ceased licensed activities entirely before this date. Annual fees for licensees who filed for termination of a license, downgrade of a license, or for a possession-only license during the FY and for new licenses issued during the FY will be prorated in accordance with the provisions of § 171.17. If a person holds more than one license, certificate, registration, or approval, the annual fee(s) will be assessed for each license, certificate, registration, or approval held by that person. For licenses that authorize more than one activity on a single license (*e.g.,* human use and irradiator activities), annual fees will be assessed for each category applicable to the license. Licensees paying annual fees under Category 1.A.(1) are not subject to the annual fees for Categories 1.C. and 1.D. for sealed sources authorized in the license.

[2] Payment of the prescribed annual fee does not automatically renew the license, certificate, registration, or approval for which the fee is paid. Renewal applications must be filed in accordance with the requirements of parts 30, 40, 70, 71, 72, or 76 of this chapter.

[3] Each FY, fees for these materials licenses will be calculated and assessed in accordance with § 171.13 and will be published in the FEDERAL REGISTER for notice and comment.

[4] Other facilities include licenses for extraction of metals, heavy metals, and rare earths.

[5] There are no existing NRC licenses in these fee categories. If NRC issues a license for these categories, the Commission will consider establishing an annual fee for this type of license.

[6] Standardized spent fuel facilities, 10 CFR parts 71 and 72 Certificates of Compliance and related Quality Assurance program approvals, and special reviews, such as topical reports, are not assessed an annual fee because the generic costs of regulating these activities are primarily attributable to users of the designs, certificates, and topical reports.

[7] Licensees in this category are not assessed an annual fee because they are charged an annual fee in other categories while they are licensed to operate.

[8] No annual fee is charged because it is not practical to administer due to the relatively short life or temporary nature of the license.

[9] Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions that also hold nuclear medicine licenses under Categories 7.B. or 7.C.

[10] This includes Certificates of Compliance issued to the Department of Energy that are not funded from the Nuclear Waste Fund.

[11] See § 171.15(c).

[12] See § 171.15(c).

[13] No annual fee is charged for this category because the cost of the general license registration program applicable to licenses in this category will be recovered through 10 CFR part 170 fees.

[14] Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. (This exception does not apply if the radium sources are possessed for storage only.)

(e) The fee-relief adjustment allocated to annual fees includes the budgeted resources for the activities listed in paragraph (e)(1) of this section, plus the total budgeted resources for the activities included in paragraphs (e)(2) and (e)(3) of this section, as reduced by the appropriations NRC receives for these types of activities. If the NRC's appropriations for these types of activities are greater than the budgeted resources for the activities included in paragraphs (e)(2) and (e)(3) of this section for a given FY, a negative fee-relief adjustment (or annual fee reduction) will be allocated to annual fees. The activities comprising the FY 2011 fee-relief adjustment are as follows:

* * * * *

Dated at Rockville, Maryland, this 2nd day of June 2011.

For the Nuclear Regulatory Commission.

J. E. Dyer,

Chief Financial Officer.

Note: This appendix will not appear in the code of Federal regulations.

Appendix A to Final Rule, Revision of Fee Schedules; Fee Recovery for Fiscal Year 2011—Regulatory Flexibility Analysis for the Final Amendments to 10 CFR Part 170 (License Fees) and 10 CFR Part 171 (Annual Fees)

I. Background

The Regulatory Flexibility Act (RFA), as amended at 5 U.S.C. 601 *et seq.,* requires that agencies consider the impact of their rulemakings on small entities and, consistent with applicable statutes, consider alternatives to minimize these impacts on the businesses, organizations, and government jurisdictions to which they apply.

The Nuclear Regulatory Commission (NRC or the Commission) has established standards for determining which NRC licensees qualify as small entities (Title 10 of the Code of Federal Regulations (10 CFR) 2.810). These standards were based on the Small Business Administration's most common receipts-based size standards and provides for business concerns that are manufacturing entities. The NRC uses the size standards to reduce the impact of annual fees on small entities by establishing a licensee's eligibility to qualify for a maximum small entity fee. The small entity fee categories in § 171.16(c) of this rule are based on the NRC's size standards.

The NRC is required each year, under the Omnibus Budget Reconciliation Act of 1990 (OBRA–90), as amended, to recover approximately 90 percent of its budget authority (less amounts appropriated from the Nuclear Waste Fund (NWF) and for other activities specifically removed from the fee base), through fees to NRC licensees and applicants. The OBRA–90 requires that the schedule of charges established by rulemaking should fairly and equitably allocate the total amount to be recovered from the NRC's licensees and be assessed under the principle that licensees who require the greatest expenditure of agency resources pay the greatest annual charges. Since FY 1991, the NRC has complied with OBRA–90 by issuing a final rule that amends its fee regulations. These final rules have established the methodology used by the NRC in identifying and determining the fees to be assessed and collected in any given FY.

The Commission is rebaselining its 10 CFR part 171 annual fees in FY 2011. As compared with FY 2010 annual fees, the FY 2011 final rebaselined fees are higher for four classes of licensees (spent fuel storage and reactors in decommissioning facilities, research and test reactors, fuel facilities, and transportation), and lower for one class of licensees (power reactors). Within the uranium recovery fee class, the final annual fees for most licensees decrease, while the final annual fee for one fee category increases. The annual fee increases for most fee categories in the materials users' fee class.

The Small Business Regulatory Enforcement Fairness Act (SBREFA) provides Congress with the opportunity to review agency rules before they go into effect. Under this legislation, the NRC annual fee rule is considered a ''major'' rule and must be reviewed by Congress and the Comptroller General before the rule becomes effective.

The SBREFA also requires that an agency prepare a written compliance guide to assist small entities in complying with each rule for which a Regulatory Flexibility Analysis (RFA) is prepared. As required by law, this analysis and the small entity compliance guide (Attachment 1) have been prepared for the FY 2011 fee rule.

II. Impact on Small Entities

The fee rule results in substantial fees charged to those individuals, organizations, and companies licensed by the NRC, including those licensed under the NRC materials program. Comments received on previous fee rulemakings and the small entity certifications in response to previous final fee rules indicate that licensees qualifying as small entities under the NRC's size standards are primarily materials licensees. Therefore, this analysis will focus on the economic impact of fees on materials licensees. In FY 2010, about 29 percent of these licensees (approximately 921 licensees) qualified as small entities.

Commenters on previous fee rulemakings consistently indicated that the following would occur if the final annual fees were not modified:

1. Large firms would gain an unfair competitive advantage over small entities. Commenters noted that small and very small companies (''Mom and Pop'' operations) would find it more difficult to absorb the annual fee than a large corporation or a high-volume type of operation. In competitive markets, such as soil testing, annual fees would put small licensees at an extreme competitive disadvantage with their much larger competitors because the final fees would be identical for both small and large firms.

2. Some firms would be forced to cancel their licenses. A licensee with receipts of less than $500,000 per year stated that the final rule would, in effect, force it to relinquish its soil density gauge and license, thereby reducing its ability to do its work effectively. Other licensees, especially well-loggers, noted that the increased fees would force small businesses to abandon the materials license altogether. Commenters estimated that the final rule would cause roughly 10 percent of the well-logging licensees to terminate their licenses immediately and approximately 25 percent to terminate before the next annual assessment.

3. Some companies would go out of business.

4. Some companies would have budget problems. Many medical licensees noted that, along with reduced reimbursements, the final increase of the existing fees and the introduction of additional fees would significantly affect their budgets. Others noted that, in view of the cuts by Medicare and other third party carriers, the fees would produce a hardship difficult for some facilities to meet.

Over 3,000 licenses, approvals, and registration terminations have been requested since the NRC first established annual fees for materials licenses. Although some terminations were requested because the license was no longer needed or could be combined with registrations, indications are that the economic impact of the fees caused other terminations.

To alleviate the significant impact of the annual fees on a substantial number of small entities, the NRC considered the following alternatives in accordance with the RFA in developing each of its fee rules since FY 1991.

1. Base fees on some measure of the amount of radioactivity possessed by the licensee (*e.g.,* number of sources).

2. Base fees on frequency of use of licensed radioactive material (*e.g.,* volume of patients).

3. Base fees on the NRC size standards for small entities.

The NRC has reexamined its previous evaluations of these alternatives and continues to believe that a maximum fee for small entities is the most appropriate and effective option for reducing the impact of fees on small entities.

III. Maximum Fee

The SBREFA and its implementing guidance do not provide specific guidelines on what constitutes a significant economic impact on a small entity. In developing the maximum small entity annual fee in FY 1991, the NRC examined 10 CFR part 170 licensing and inspection fees and Agreement State fees for fee categories which were expected to have a substantial number of small entities. Six Agreement States (Washington, Texas, Illinois, Nebraska, New York, and Utah) were used as benchmarks in the establishment of the maximum small entity annual fee in FY 1991.

The NRC maximum small entity fee was established as an annual fee only. In addition to the annual fee, NRC small entity licensees were required to pay amendment, renewal and inspection fees. In setting the small entity annual fee, NRC ensured that the total amount small entities paid would not exceed the maximum paid in the six benchmark Agreement States.

Of the six benchmark States, the NRC used Washington's maximum Agreement State fee of $3,800 as the ceiling for total fees. Thus, the NRC's small entity fee was developed to ensure that the total fees paid by NRC small entities would not exceed $3,800. Given the NRC's FY 1991 fee structure for inspections, amendments, and renewals, a small entity annual fee established at $1,800 allowed the total fee (small entity annual fee plus yearly average for inspections, amendments, and renewal fees) for all categories to fall under the $3,800 ceiling.

In FY 1992, the NRC introduced a second, lower tier to the small entity fee in response to concerns that the $1,800 fee, when added to the license and inspection fees, still imposed a significant impact on small entities with relatively low gross annual receipts. For purposes of the annual fee, each small entity size standard was divided into an upper and lower tier. Small entity licensees in the upper tier continued to pay an annual fee of $1,800, while those in the lower tier paid an annual fee of $400.

Based on the changes that had occurred since FY 1991, the NRC reanalyzed its maximum small entity annual fees in FY 2000 and determined that the small entity fees should be increased by 25 percent to reflect the increase in the average fees paid by other materials licensees since FY 1991, as well as changes in the fee structure for materials licensees. The structure of fees NRC charged its materials licensees changed during the period between 1991 and 1999. Costs for materials license inspections, renewals, and amendments, which were previously recovered through part 170 fees for services, are now included in the part 171 annual fees assessed to materials licensees. Because of the 25 percent increase, in FY 2000 the maximum small entity annual fee increased from $1,800 to $2,300. However, despite the increase, total fees for many small entities were reduced because they no longer paid part 170 fees. Costs not recovered from small entities were allocated to other materials licensees and to power reactors.

While reducing the impact on many small entities, the NRC determined that the maximum annual fee of $2,300 for small entities could continue to have a significant impact on materials licensees with relatively low annual gross receipts. Therefore, the NRC continued to provide the lower-tier small entity annual fee for small entities with relatively low gross annual receipts, manufacturing concerns, and for educational institutions not State or publicly supported with fewer than 35 employees. The NRC also increased the lower-tier small entity fee by 25 percent, the same percentage increase to the maximum small entity annual fee, resulting in the lower-tier small entity fee increasing from $400 to $500 in FY 2000.

The NRC stated in the RFA for the FY 2001 final fee rule that it would reexamine the small entity fees every 2 years, in the same years in which it conducts the biennial review of fees as required by the Chief Financial Officers Act. Accordingly, the NRC examined the small entity fees again in FY 2003 and FY 2005, determining that a change was not warranted to those fees established in FY 2001.

As part of the small entity review in FY 2007, the NRC also considered whether it should establish reduced fees for small entities under part 170. The NRC received one comment requesting that small entity fees be considered for certain export licenses, particularly in light of the recent increases to part 170 fees for these licenses. Because the NRC's part 170 fees are not assessed to a licensee or applicant on a regular basis (*i.e.,* they are only assessed when a licensee or applicant requests a specific service from the NRC), the NRC does not believe that the impact of its part 170 fees warrants a fee reduction for small entities, in addition to the part 171 small entity fee reduction. Regarding export licenses, the NRC notes that interested parties can submit a single application for a broad scope, multi-year license that permits exports to multiple countries. Because the NRC charges fees per application, this process minimizes the fees for export applicants. Because a single NRC fee can cover numerous exports, and because there are a limited number of entities who apply for these licenses, the NRC does not anticipate that the part 170 export fees will have a significant impact on a substantial number of small entities. Therefore, the NRC

retained the $2,300 small entity annual fee and the $500 lower-tier small entity annual fee for FY 2007 and FY 2008.

The NRC conducted an in-depth biennial review of the FY 2009 small entity fees. The review noted significant changes between FY 2000 and FY 2008 in both the external and internal environment which impacted fees for NRC's materials users licensees. Since FY 2000, small entity licensees in the upper tier had increased approximately 53 percent. In addition, due to changes in the law, NRC is now required to recover only 90 percent of its budget authority compared to 100 percent recovery required in FY 2000. This 10 percent fee-relief has influenced the materials users' annual fees. A decrease in the NRC's budget allocation to the materials users also influenced annual fees in FY 2007 and FY 2008.

Based on the review, the NRC changed the methodology for reviewing small entity fees. The NRC determined the maximum small entity fee should be adjusted each biennial year using a fixed percentage of 39 percent applied to the prior 2-year weighted average of materials users fees for all fee categories which have small entity licensees. The 39 percent was based on the small entity annual fee for FY 2005, which was the first year the NRC was required to recover only 90 percent of its budget authority. The FY 2005 small entity annual fee of $2,300 was 39 percent of the 2-year weighted average for all fee categories in FY 2005 and FY 2006 that had an upper-tier small entity licensee. The new methodology allows small entity licensees to be able to predict changes in their fee in the biennial year based on the materials users' fees for the previous 2 years. Using a 2-year weighted average smoothes the fluctuations caused by programmatic and budget variables and reflects the importance of the fee categories with the majority of small entities. The agency also determined the lower-tier annual fee should remain at 22 percent of the maximum small entity annual fee. In FY 2009, the NRC decreased the maximum small entity fee from $2,300 to $1,900 and decreased the lower-tier annual fee from $500 to $400.

In FY 2011, the NRC reexamined the small entity fee, including the new methodology developed in FY 2009. Per the methodology used in FY 2009, the agency computed the small entity fee by using a fixed percentage of 39 percent applied to the prior 2-year weighted average of materials users' fees. This resulted in an upper-tier small entity fee amount that was 74 percent higher than the current fee of $1,900, a reflection of the increase in annual fees for the materials users licensees for the past 2 years. Implementing this increase would have a disproportionate impact upon small NRC licensees. Therefore in FY 2011, NRC has decided to limit the increase for upper tier fees to $2,300, a 21 percent increase, and the lower tier fee to $500, a 25 percent increase. This increase in the small entity fee partially reflects the changes to the annual fee for the materials users for the previous 2 years.

IV. Summary

The NRC has determined that the 10 CFR part 171 annual fees significantly impact a substantial number of small entities. A maximum fee for small entities strikes a balance between the requirement to recover 90 percent of the NRC budget and the requirement to consider means of reducing the impact of the fee on small entities. Based on its RFA, the NRC concludes that a maximum annual fee of $2,300 for small entities and a lower-tier small entity annual fee of $500 for small businesses and not-for-profit organizations with gross annual receipts of less than $450,000, small governmental jurisdictions with a population of fewer than 20,000, small manufacturing entities that have fewer than 35 employees, and educational institutions that are not State or publicly supported and have fewer than 35 employees, reduces the impact on small entities. At the same time, these reduced annual fees are consistent with the objectives of OBRA–90. Thus, the fees for small entities maintain a balance between the objectives of OBRA–90 and the RFA.

Attachment 1 to Appendix A—U. S. Nuclear Regulatory Commission Small Entity Compliance Guide; Fiscal Year 2011

Contents

I. Introduction
II. NRC Definition of Small Entity
III. NRC Small Entity Fees
IV. Instructions for Completing NRC Form 526

I. Introduction

The Small Business Regulatory Enforcement Fairness Act (SBREFA) requires all Federal agencies to prepare a written compliance guide for each rule for which the agency is required by U.S.C. 604 to prepare a regulatory flexibility analysis. Therefore, in compliance with the law, Attachment 1 to the Regulatory Flexibility Analysis is the small entity compliance guide for FY 2011.

Licensees may use this guide to determine whether they qualify as a small entity under NRC regulations and are eligible to pay reduced FY 2011 annual fees assessed under Title 10 of the Code of Federal Regulations (10 CFR) part 171. The U.S. Nuclear Regulatory Commission (NRC) has established two tiers of annual fees for those materials licensees who qualify as small entities under the NRC's size standards.

Licensees who meet the NRC's size standards for a small entity (listed in 10 CFR 2.810) must submit a completed NRC Form 526 ACertification of Small Entity Status for the Purposes of Annual Fees Imposed under 10 CFR part 171'' to qualify for the reduced annual fee. This form can be accessed on the NRC's Web site at *http://www.nrc.gov.* The form can then be accessed by selecting ''About NRC'', ''How We Regulate'', ''Licensing'', ''License Fees'', then ''Payment Terms, Options, and Forms,'' selecting NRC Form 526. For licensees who cannot access the NRC's Web site, NRC Form 526 may be obtained by calling the License Fee Billing Help Desk at 301–415–7554, or by e-mailing the fee staff at *fees.resource@nrc.gov.*

The completed form, the appropriate small entity fee, and the payment copy of the invoice should be mailed to the U.S. Nuclear Regulatory Commission, Accounts Receivable/Payable Branch, at the address indicated on the invoice. Failure to file the NRC small entity certification Form 526 in a timely manner may result in the denial of any refund that might otherwise be due.

II. NRC Definition of Small Entity

For purposes of compliance with its regulations (10 CFR 2.810), the NRC has defined a small entity as follows:

(1) *Small business*—a for-profit concern and is a (a) concern that provides a service or a concern that is not engaged in manufacturing with average gross receipts of $6.5 million or less over its last 3 completed fiscal years; or (b) manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months;

(2) *Small organization*—a not-for-profit organization which is independently owned and operated and has annual gross receipts of $6.5 million or less;

(3) *Small governmental jurisdiction*—a government of a city, county, town, township, village, school district, or special district with a population of less than 50,000; and

(4) *Small educational institution*—an educational institution that is (a) supported by a qualifying small governmental jurisdiction; or (b) not state or publicly supported and has 500 or fewer employees.[1]

To further assist licensees in determining if they qualify as a small entity, the following guidelines are provided, which are based on the Small Business Administration's regulations (13 CFR part 121).

(1) A small business concern is an independently owned and operated entity which is not considered dominant in its field of operations.

(2) The number of employees means the total number of employees in the parent company, any subsidiaries and/or affiliates, including both foreign and domestic locations (*i.e.,* not solely the number of employees working for the licensee or conducting NRC-licensed activities for the company).

(3) Gross annual receipts include all revenue received or accrued from any source, including receipts of the parent company, any subsidiaries and/or affiliates, and account for both foreign and domestic locations. Receipts include all revenues from sales of products and services, interest, rent, fees, and commissions from whatever sources derived (*i.e.,* not solely receipts from NRC-licensed activities).

(4) A licensee who is a subsidiary of a large entity, including a foreign entity, does not qualify as a small entity.

[1] An educational institution referred to in the size standards is an entity whose primary function is education, whose programs are accredited by a nationally recognized accrediting agency or association, who is legally authorized to provide a program of organized instruction or study, who provides an educational program for which it awards academic degrees, and whose educational programs are available to the public.

III. NRC Small Entity Fees

In 10 CFR 171.16(c), the NRC has established two tiers of fees for licensees that qualify as a small entity under the NRC's size standards. The fees are as follows:

	Maximum annual fee per licensed category
Small Businesses Not Engaged in Manufacturing (Average gross receipts over last 3 completed fiscal years):	
$450,000 to $6.5 million	$2,300
Less than $450,000	500
Small Not-For-Profit Organizations (Annual Gross Receipts):	
$450,000 to $6.5 million	2,300
Less than $450,000	500
Manufacturing entities that have an average of 500 employees or fewer:	
35 to 500 employees	2,300
Fewer than 35 employees	500
Small Governmental Jurisdictions (Including publicly supported educational institutions) (Population):	
20,000 to 50,000	2,300
Fewer than 20,000	500
Educational Institutions that are not State or publicly supported, and have 500 employees or fewer:	
35 to 500 employees	2,300
Fewer than 35 employees	500

IV. Instructions for Completing NRC Small Entity Form 526

1. Complete all items on NRC Form 526 as follows: (*Note:* Incomplete or improperly completed forms will be returned as unacceptable.)

(a) Enter the license number and invoice number exactly as they appear on the annual fee invoice.

(b) Enter the North American Industry Classification System.

(c) Enter the licensee's name and address exactly as they appear on the invoice. Annotate name and/or address changes for billing purposes on the payment copy of the invoice—include contact's name, telephone number, e-mail address, and company Web site address. Correcting the name and/or address on NRC Form 526 or on the invoice does not constitute a request to amend the license.

(d) Check the appropriate size standard under which the licensee qualifies as a small entity. Check one box only. Note the following:

(i) A licensee who is a subsidiary of a large entity, including foreign entities, does not qualify as a small entity. The calculation of a firm's size includes the employees or receipts of all affiliates. Affiliation with another concern is based on the power to control, whether exercised or not. Such factors as common ownership, common management, and identity of interest (often found in members of the same family), among others, are indications of affiliation. The affiliated business concerns need not be in the same line of business.

(ii) Gross annual receipts, as used in the size standards, include all revenue received or accrued by your company from all sources, regardless of the form of the revenue and not solely receipts from licensed activities.

(iii) NRC's size standards on a small entity are based on the Small Business Administration's regulations (13 CFR part 121).

(iv) The size standards apply to the licensee, not to the individual authorized users who may be listed in the license.

2. If the invoice states the ''Amount Billed Represents 50% Proration,'' the amount due is not the prorated amount shown on the invoice but rather one-half of the maximum small entity annual fee shown on NRC Form 526 for the size standard under which the licensee qualifies (either $1,150 or $250) for each category billed.

3. If the invoice amount is less than the reduced small entity annual fee shown on this form, pay the amount on the invoice; there is no further reduction. In this case, do not file NRC Form 526. However, if the invoice amount is greater than the reduced small entity annual fee, file NRC Form 526 and pay the amount applicable to the size standard you checked on the form.

4. The completed NRC Form 526 must be submitted with the required annual fee payment and the ''Payment Copy'' of the invoice to the address shown on the invoice.

5. Section 171.16(c) states licensees shall submit a proper certification with its annual fee payment each year. Failure to submit NRC Form 526 at the time the annual fee is paid will require the licensee to pay the full amount of the invoice.

The NRC sends invoices to its licensees for the full annual fee, even though some licensees qualify for reduced fees as small entities. Licensees who qualify as small entities and file NRC Form 526, which certifies eligibility for small entity fees, may pay the reduced fee, which is either $2,300 or $500 for a full year, depending on the size of the entity, for each fee category shown on the invoice. Licensees granted a license during the first 6 months of the fiscal year, and licensees who file for termination or for a ''possession-only'' license and permanently cease licensed activities during the first 6 months of the fiscal year, pay only 50 percent of the annual fee for that year. Such invoices state that the ''amount billed represents 50% proration.''

Licensees must file a new small entity form (NRC Form 526) with the NRC each fiscal year to qualify for reduced fees in that year. Because a licensee's ''size,'' or the size standards, may change from year to year, the invoice reflects the full fee, and licensees must complete and return NRC Form 526 for the fee to be reduced to the small entity fee amount. LICENSEES WILL NOT RECEIVE A NEW INVOICE FOR THE REDUCED AMOUNT. The completed NRC Form 526, the payment of the appropriate small entity fee, and the ''Payment Copy'' of the invoice should be mailed to the U.S. Nuclear Regulatory Commission, Accounts Receivable/Payable Branch, at the address indicated on the invoice.

If you have questions regarding the NRC's annual fees, please contact the License Fee Billing Help Desk at 301–415–7554, e-mail the fee staff at *fees.resource@nrc.gov,* or write to the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Office of the Chief Financial Officer.

False certification of small entity status could result in civil sanctions being imposed by the NRC under the Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801 *et. seq.* NRC's implementing regulations are found at 10 CFR part 13.

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Part IV

National Labor Relations Board

29 CFR Parts 101, 102 and 103

Representation—Case Procedures; Proposed Rule

NATIONAL LABOR RELATIONS BOARD

29 CFR Parts 101, 102 and 103

RIN 3142–AA08

Representation—Case Procedures

AGENCY: National Labor Relations Board.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: As part of its ongoing efforts to more effectively administer the National Labor Relations Act (the Act or the NLRA) and to further the purposes of the Act, the National Labor Relations Board (the Board) proposes to amend its rules and regulations governing the filing and processing of petitions relating to the representation of employees for purposes of collective bargaining with their employer. The Board believes that the proposed amendments would remove unnecessary barriers to the fair and expeditious resolution of questions concerning representation. The proposed amendments would simplify representation-case procedures and render them more transparent and uniform across regions, eliminate unnecessary litigation, and consolidate requests for Board review of regional directors' pre- and post-election determinations into a single, post-election request. The proposed amendments would allow the Board to more promptly determine if there is a question concerning representation and, if so, to resolve it by conducting a secret ballot election.

DATES: Comments regarding this proposed rule must be received by the Board on or before August 22, 2011. Comments replying to comments submitted during the initial comment period must be received by the Board on or before September 6, 2011. Reply comments should be limited to replying to comments previously filed by other parties. No late comments will be accepted. The Board intends to issue a notice of public hearing to be held in Washington, DC, on July 18–19, at which interested persons would be invited to share their views on the proposed amendments and to make any other proposals concerning the Board's representation case procedures.

ADDRESSES: You may submit comments identified by 3142–AA08 only by the following methods:

Internet—Federal eRulemaking Portal. Electronic comments may be submitted through *http://www.regulations.gov.* To locate the proposed rule, search ''documents open for comment'' and use key words such as ''National Labor Relations Board'' or ''representation-case procedures'' to find documents accepting comments. Follow the instructions for submitting comments.

Delivery—Comments should be sent by mail or hand delivery to: Lester A. Heltzer, Executive Secretary, National Labor Relations Board, 1099 14th Street, NW., Washington, DC 20570. Because of security precautions, the Board continues to experience delays in U.S. mail delivery. You should take this into consideration when preparing to meet the deadline for submitting comments. The Board encourages electronic filing. It is not necessary to send comments if they have been filed electronically with regulations.gov. If you send comments, the Board recommends that you confirm receipt of your delivered comments by contacting (202) 273–1067 (this is not a toll-free number). Individuals with hearing impairments may call 1–866–315–6572 (TTY/TDD).

Only comments submitted through *http://www.regulations.gov,* hand delivered, or mailed will be accepted; ex parte communications received by the Board will be made part of the rulemaking record and will be treated as comments only insofar as appropriate. Comments will be available for public inspection at *http://www.regulations.gov* and during normal business hours (8:30 a.m. to 5 p.m. EST) at the above address.

The Board will post, as soon as practicable, all comments received on *http://www.regulations.gov* without making any changes to the comments, including any personal information provided. The Web site *http://www.regulations.gov* is the Federal eRulemaking portal, and all comments posted there are available and accessible to the public. The Board requests that comments include full citations or Internet links to any authority relied upon. The Board cautions commenters not to include personal information such as Social Security numbers, personal addresses, telephone numbers, and e-mail addresses in their comments, as such submitted information will become viewable by the public via the *http://www.regulations.gov* Web site. It is the commenter's responsibility to safeguard his or her information. Comments submitted through *http://www.regulations.gov* will not include the commenter's e-mail address unless the commenter chooses to include that information as part of his or her comment.

FOR FURTHER INFORMATION CONTACT: Lester A. Heltzer, Executive Secretary, National Labor Relations Board, 1099 14th Street, NW., Washington, DC 20570, (202) 273–1067 (this is not a toll-free number), 1–866–315–6572 (TTY/TDD).

SUPPLEMENTARY INFORMATION:

I. Background

Section 7 of the National Labor Relations Act (the Act or the NLRA), 29 U.S.C. 157, vests in employees the right ''to bargain collectively through representatives of their own choosing * * * and to refrain from * * * such activity.'' The Act vests in the National Labor Relations Board (the Board) a central role in the effectuation of that right when employers, employees, and labor organizations are unable to agree on whether the employer should recognize a labor organization as the representative of the employees. Section 9 of the Act, 29 U.S.C. 159, gives the Board authority to determine if such a ''question of representation'' exists and, if so, to resolve the question by conducting ''an election by secret ballot.''

Congress left the procedures for determining if a question of representation exists and for conducting secret ballot elections almost entirely within the discretion of the Board. The Supreme Court has repeatedly recognized that ''Congress has entrusted the Board with a wide degree of discretion in establishing the procedure and safeguards necessary to insure the fair and free choice of bargaining representatives by employees.'' *NLRB* v. *A.J. Tower Co.,* 329 U.S. 324, 330 (1946). ''The control of the election proceeding, and the determination of the steps necessary to conduct that election fairly were matters which Congress entrusted to the Board alone.'' *NLRB* v. *Waterman S.S. Co.,* 309 U.S. 206, 226 (1940); see also *Southern S.S. Co.* v. *NLRB,* 316 U.S. 31, 37 (1942).

Since 1935, the Board has exercised its discretion to establish standard procedures in representation cases largely through promulgation and revision of rules and regulations or internal policies.[1] Thus, 29 CFR part

[1] The Board's failure to rely on rulemaking in other areas has met widespread scholarly criticism. See R. Alexander Acosta, *Rebuilding the Board: An Argument for Structural Change, over Policy Prescriptions, at the NLRB,* 5 FIU L. Rev. 347, 351–52 (2010); Merton C. Bernstein, *The NLRB's Adjudication-Rule Making Dilemma Under the Administrative Procedure Act,* 79 Yale L.J. 571 (1970); Samuel Estreicher, *Policy Oscillation at the Labor Board: A Plea for Rulemaking,* 37 Admin. L. Rev. 163 (1985); Jeffrey S. Lubbers, *The Potential of Rulemaking by the NLRB,* 5 FIU L. Rev. 411, 414–17, 435 (Spring 2010); Kenneth Kahn, *The NLRB and Higher Education: The Failure of Policymaking Through Adjudication,* 21 UCLA L. Rev. 63 (1973); Charles J. Morris, *The NLRB in the Dog House—Can*

102, subpart C sets forth the Board's Rules and Regulations governing ''Procedure Under Section 9(c) of the Act for the Determination of Questions Concerning Representation of Employees and for Clarification of Bargaining Units and for Amendment of Certifications Under Section 9(b) of the Act.'' Subparts D and E set forth related rules and regulations governing ''Procedures for Unfair Labor Practice and Representation Cases Under Section 8(b)(7) and 9(c) of the Act'' and ''Procedure for Referendum Under Section 9(e) of the Act.'' 29 CFR part 101, subparts C, D and E set forth the Board's Statements of Procedures in the same three types of cases. The Board's Casehandling Manual at Sections 11000 through 11886 describes procedures in representation cases in greater detail, including the mechanics of elections.[2]

Congress intended that the Board adopt procedures that permit questions concerning representation to be resolved both quickly and fairly. As the Supreme Court has noted, ''[T]he Board must adopt policies and promulgate rules and regulations in order that employees' votes may be recorded accurately, efficiently and speedily.'' *A.J. Tower Co.,* 329 U.S. at 330–31. The Board has repeatedly recognized ''the Act's policy of expeditiously resolving questions concerning representation.''[3] ''In * * * representation proceedings under Section 9,'' the Board has observed, ''time is of the essence if Board processes are to be effective.''[4] Indeed, the Board's Casehandling Manual stresses that ''[t]he expeditious processing of petitions filed pursuant to the Act represents one of the most significant aspects of the Agency's operations.''[5]

Expeditious resolution of questions concerning representation is central to the statutory design because Congress found that ''refusal by some employers to accept the procedure of collective bargaining lead[s] to strikes and other forms of industrial strife and unrest, which have the intent or the necessary effect of burdening and obstructing commerce.''[6] Thus, Congress found that the Board's expeditious processing of representation petitions and, when appropriate, conduct of elections would ''safeguard[] commerce from injury, impairment or interruption.''[7]

One of the primary purposes of the original Wagner Act was to avoid ''the long delays in the procedure * * * resulting from applications to the federal appellate courts for review of orders for elections.'' *AFL* v. *NLRB,* 308 U.S. 401, 409 (1940). The Senate Committee Report explained that one of the ''weaknesses in existing law'' was ''that the Government can be delayed indefinitely before it takes the first step toward industrial peace'' by conducting an election.[8] For this reason, Congress did not provide for direct judicial review of either interlocutory orders or final certifications or dismissals in representation proceedings conducted under section 9 of the Act. Rather, in order to insure that elections were conducted promptly, judicial review was permitted only after issuance of an order under section 10 relying, in part, on the Board's certification under section 9.

A. Evolution of Board Regulation of Representation Case Procedures

1. Legislative and Administrative Delegation of Authority To Process Petitions in Order To Expedite Resolution of Questions Concerning Representation

The Board initially exercised its discretion over the conduct of representation elections through a procedure under which, in the event the parties could not agree concerning the conduct of an election, an employee of one of the Board's regional offices would develop a record at a pre-election hearing.[9] At the close of the hearing, the record was forwarded to the Board in Washington, DC, which either directed an election or made some other disposition of the matter.[10] However, requiring the Board itself to address all of the myriad disputes arising out of the thousands of representation petitions filed annually resulted in significant delays.

Accordingly, in 1959, as part of the amendments of the NLRA effected by the Labor-Management Reporting and Disclosure Act, Congress revised Section 3(b) of the Act to authorize the Board to delegate its election-related duties to the directors of the Board's regional offices, subject to discretionary Board review.[11] Section 3(b) provides:

> The Board is * * * authorized to delegate to its regional directors its powers under section 9 to determine the unit appropriate for the purpose of collective bargaining, to investigate and provide for hearings, and determine whether a question of representation exists, and to direct an election or take a secret ballot under subsection (c) or (e) of section 9 and certify the results thereof, except that upon the filing of a request therefor with the Board by any interested person, the Board may review any action of a regional director delegated to him under this paragraph, but such a review shall not, unless specifically ordered by the Board, operate as a stay of any action taken by the regional director.

As Senator Goldwater, a member of the Conference Committee which added the new section to the amendments, explained, ''[Section 3(b)] is a new provision, not in either the House or Senate bills, designed to expedite final disposition of cases by the Board, by turning over part of its caseload to its regional directors for final determination. * * * This authority to delegate to the regional directors is designed, as indicated, to speed the work of the Board.''[12]

Soon after the authorizing amendment was adopted in 1959, the Board made the permitted delegation to its regional directors by amending its rules and regulations.[13] Since the delegation, the Board's regional directors have resolved pre-election disputes and directed elections, subject to a procedure through which aggrieved parties can seek Board review of regional directors' pre-election decisions.[14] The Board's amended rules made such review discretionary, only to be granted in compelling circumstances, and that process was subsequently upheld by the Supreme Court.[15]

As intended by Congress, the implementation of the new procedure led to a significant decrease in the time it took to conduct representation

an Old Board Learn New Tricks?, 24 San Diego L. Rev. 9 (1987); Cornelius Peck, *The Atrophied Rulemaking Powers of the National Labor Relations Board,* 70 Yale L.J. 729 (1961); Cornelius J. Peck, *A Critique of the National Labor Relations Board's Performance in Policy Formulation: Adjudication and Rule-Making,* 117 U. Pa. L. Rev. 254 (1968); David L. Shapiro, *The Choice of Rulemaking or Adjudication in the Development of Administrative Policy,* 78 Harv. L. Rev. 921 (1965); Carl S. Silverman, *The Case for the National Labor Relations Board's Use of Rulemaking in Asserting Jurisdiction,* 25 Lab. L.J. 607 (1974); and Berton B. Subrin, *Conserving Energy at the Labor Board: The Case for Making Rules on Collective Bargaining Units,* 32 Lab. L.J. 105 (1981).

[2] The Casehandling Manual is prepared by the Board's General Counsel and is not binding on the Board. *Hempstead Lincoln,* 349 NLRB 552, 552 n.4 (2007); *Pacific Grain Products,* 309 NLRB 690, 691 n.5 (1992).

[3] See, *e.g., Northeastern University,* 261 NLRB 1001, 1002 (1982).

[4] *Tropicana Products, Inc.,* 122 NLRB 121, 123 (1958).

[5] Pt. 2, Representation Proceedings, Section 11000.

[6] 29 U.S.C. 151.

[7] *Id.*

[8] S. Rep. No. 573, 74th Cong., 1st Sess. pp. 5–6. See also H. Rep. No. 1147, 74th Cong., 1st Sess. p. 6.

[9] 29 CFR 102.63 and 102.64 (1959).

[10] 29 CFR 102.67 and 102.68 (1959).

[11] Public Law 86–257 (codified as amended in 29 U.S.C. 153(b)).

[12] 105 Cong. Rec. 19770.

[13] 26 FR 3885 (May 4, 1961).

[14] 29 CFR 102.67 (1961).

[15] *Magnesium Casting Co.* v. *NLRB,* 401 U.S. 137, 142 (1971).

elections. Immediately following the Board's amendment of its rules in 1961, the median number of days necessary to process election petitions to a decision and direction of election was roughly cut in half.[16] By 1975, the Board was conducting elections in a median of 50 days from the filing of an election petition.[17]

The Board's next major improvement in the efficiency of its election procedures came in 1977. After a decade and a half of experience with the request for review procedure, the Board again amended its rules to reduce delay in elections after the Board granted review of a regional director's decision and direction of election or a preliminary ruling.[18] Specifically, the Board established a procedure whereby the regional directors would proceed to conduct elections as directed, notwithstanding the Board's decision to grant review, unless the Board ordered otherwise. Under this procedure, the regional director impounds the ballots at the conclusion of the election, and delays tallying them until the Board issues its decision. Although this change did not have a significant effect on the overall median number of days from petition to election, it substantially decreased the time it took to conduct elections in the small number of cases in which the Board granted review.[19] These procedures remain in place today.

The Board continued to focus on processing representation petitions expeditiously in the years following implementation of the vote and impound procedure. As a result, more than 90 percent of elections were conducted within 56 days of the filing of a petition during the last decade, with a median time of 37–38 days between petition and election.[20]

Notably, however, the nature of the Board's review of regional directors' decisions varies, depending on whether the decision was issued before or after the election.[21] As described above, the Board has exercised its authority to delegate to its regional directors the task of processing petitions through the conduct of an election subject only to discretionary Board review. In contrast, the current rules provide that any party, unless it has waived the right in a pre-election agreement, may in most cases obtain Board review of a regional director's resolution of any post-election dispute, whether concerning challenges to the eligibility of a voter or objections to the conduct of the election or conduct affecting the results of an election. The right to review of regional directors' post-election decisions has caused extended delay of final certification of election results in many instances.[22]

2. Limiting the Pre-Election Hearing to Issues Genuinely in Dispute and Material to Determining if a Question Concerning Representation Exists

a. Identification and Joinder of Issues

Other than the petition, the parties to a representation proceeding under section 9 of the Act are not required to file any other form of pleading. The current regulations do not provide for any form of responsive pleading, in the nature of an answer, through which non-petitioning parties are required to give notice of the issues they intend to raise at a hearing. As a consequence, the petitioner is not required to join any such issues.

The Board has, nevertheless, developed administrative practices in an effort to identify and narrow the issues in dispute before or at a pre-election hearing. The regional director's initial letter to an employer following the filing of a petition asks the employer to state its position ''as to the appropriateness of the unit described in the petition.'' [23] In some cases, regions will conduct pre-hearing conferences either face-to-face or by telephone in an effort to identify and narrow the issues in dispute. Further, section 11217 of the Casehandling Manual provides, ''Prior to the presentation of evidence or witnesses, parties to the hearing should succinctly state on the record their positions as to the issues to be heard.'' However, none of these practices is mandatory, and they are not uniformly followed in the regions.

In *Bennett Industries, Inc.,* 313 NLRB 1363, 1363 (1994), the Board observed, ''in order to effectuate the purposes of the Act through expeditiously providing for a representation election, the Board should seek to narrow the issues and limit its investigation to areas in dispute.'' In *Bennett,* the Board sustained a hearing officer's ruling preventing an employer from introducing evidence relevant to the supervisory status of two classes of employees and included employees in the two classes in the unit without further factual inquiry when the employer refused to take a position concerning whether the employees were supervisors. The Board reasoned:

> The Board's duty to ensure due process for the parties in the conduct of the Board proceedings requires that the Board provide parties with the opportunity to present evidence and advance arguments concerning relevant issues. However, the Board also has an affirmative duty to protect the integrity of the Board's processes against unwarranted burdening of the record and unnecessary delay. Thus, while the hearing is to ensure that the record contains as full a statement of the pertinent facts as may be necessary for determination of the case (NLRB Statement of Procedure Sec. 101.20(c)), hearings are intended to afford parties ''full opportunity to present their respective *positions* and to produce the significant facts in support of their contentions.'' (emphasis added).

Id.

In *Allen Health Care Services,* 332 NLRB 1308 (2000), however, the Board held that even when an employer refuses to take a position on the appropriateness of a petitioned-for unit, the regional director must nevertheless take evidence on the issue unless the unit is presumptively appropriate. The Board held that, ''absent a stipulated agreement, presumption, or rule, the Board must be able to find—based on some record evidence—that the proposed unit is an appropriate one for bargaining before directing an election in that unit.'' *Id.* at 1309. The Board did not make clear in *Allen* whether a party that refuses to take a position on the appropriateness of a petitioned-for unit must nevertheless be permitted to introduce evidence relevant to the issue. The Casehandling Manual provides that parties should be given the following, equivocal notice in such circumstances: ''If a party refuses to state its position on an issue and no controversy exists, the

[16] See NLRB Office of the General Counsel, Summaries of Operations (Fiscal Years 1961–1962) (reporting that the ''median average'' number of days from petition to a decision and direction of election was reduced from 82 days in 1960 to 43 days in 1962).

[17] See U.S. DEP'T OF LABOR & U.S. DEP'T OF COMMERCE, COMMISSION ON THE FUTURE OF WORKER-MANAGEMENT RELATIONS, FACT-FINDING REPORT, 68, 82 (1994) (''Dunlop Commission Fact Finding'').

[18] See 42 FR 41117 (Aug. 15, 1977); Chairman's Task Force on the NLRB for 1976, Volume 1, Board Action on Recommendations of the Chairman's Task Force Memorandum to the Task Force, 3 (May 25, 1977); Chairman's Task Force, Volume 7, Task Force Report Memorandum to the Board, 10–15 (January 28, 1977).

[19] See Dunlop Commission Fact Finding, 82. Comparing the change in figures from 1975 to 1985 demonstrates that the percentage of total elections conducted more than 60 days from the filing of a petition decreased from 20.1 percent to 16.5 percent, and the percentage of total elections conducted more than 90 days from the filing of a petition decreased from 11 percent to 4.1 percent.

[20] See NLRB Office of the General Counsel, Summary of Operations (Fiscal Years 2002–2010).

[21] This is the case even when the issue addressed by the regional director is precisely the same one as, for example, when an eligibility issue is raised, litigated and decided pre-election and when the same issue is raised through a challenge and litigated and decided post-election.

[22] See, *e.g., Manhattan Crowne Plaza,* 341 NLRB 619 (2004) (exceptions concerning alleged threat contained in single, written memorandum pending before the Board for almost three years).

[23] Casehandling Manual section 11009.1(e).

party should be advised that it may be foreclosed from presenting evidence on that issue.'' Section 11217.

b. Identification of Genuine Disputes as to Material Facts

The current regulations also do not expressly provide for any form of summary judgment or offer-of-proof procedures through which the hearing officer can determine if there are genuine disputes as to any material facts, the resolution of which requires the introduction of evidence at a pre-election hearing.

The Board has developed such a procedure in reviewing post-election objections to the conduct of an election or conduct affecting the results of an election. The current regulations provide that any party filing such objections shall also file, within seven days, ''the evidence available to it to support the objections.'' 29 CFR 102.69(a). Casehandling Manual section 1132.6 further specifies, ''In addition to identifying the nature of the misconduct on which the objections are based, this submission should include a list of the witnesses and a brief description of the testimony of each.'' If an objecting party fails to file such an offer of proof or if the offer fails to describe evidence which, if introduced at a hearing, could require the election results to be overturned, the regional director dismisses the objection without a hearing. In the post-election context, the courts of appeals have uniformly endorsed the Board's refusal to hold a hearing when no party has created a genuine dispute as to any material fact. See, *e.g., NLRB* v. *Bata Shoe Co.,* 377 F.2d 821, 826 (4th Cir. 1967), *cert. denied,* 389 U.S. 917 (1967); *NLRB* v. *Air Control Products of St. Petersburg, Inc.,* 335 F.2d 245, 249 (5th Cir. 1964).

The Board has also endorsed an offer-of-proof procedure in pre-election hearings when the petitioned-for unit is presumptively appropriate. See, *e.g., Laurel Associates, Inc.,* 325 NLRB 603 (1998); *Mariah, Inc.,* 322 NLRB 586, 587 (1996). In such circumstances, the Board has sustained a hearing officer's refusal to hear evidence after an employer has either refused to make an offer of proof or offered proof not sufficient to create a genuine dispute as to facts material to the question of whether the presumption of appropriateness can be rebutted.

Because the current regulations do not describe a procedure for identifying genuine disputes as to material facts, there has been continuing uncertainty concerning the circumstances under which an evidentiary hearing is necessary. In *Angelica Healthcare Services Group, Inc.,* 315 NLRB 1320 (1995), for example, the Board reversed the decision of an acting regional director to direct an election without a hearing when an incumbent union contended there was no question concerning representation because its collective-bargaining agreement with the employer barred an election. The Board stated, ''We find that the language of Section 9(c)(1) of the Act and Section 102.63(a) of the Board's Rules required the Acting Regional Director to provide 'an appropriate hearing' prior to finding that a question concerning representation existed and directing an election.'' *Id.* at 1321. But the Board noted expressly, ''[W]e find it unnecessary to decide in this case the type of hearing that would be necessary to satisfy the Act's 'appropriate hearing' requirement.'' *Id.* at 1321 n. 6.

c. Deferral of Litigation and Resolution of Issues Not Relevant to the Determination of Whether a Question Concerning Representation Exists

Section 9(c) of the Act provides that, after the filing of a petition,

> the Board shall investigate such petition and if it has reasonable cause to believe that a question of representation affecting commerce exists, it shall provide for an appropriate hearing upon due notice. * * * If the Board finds upon the record of such hearing that such a question of representation exists, it shall direct an election by secret ballot and shall certify the results thereof.

The statutory purpose of a pre-election hearing is thus to determine if a question concerning representation exists. If such a question exists, the Board conducts an election in order to answer the question.

Whether individual employees are eligible to vote may or may not affect the outcome of an election, but it is not ordinarily relevant to the preliminary issue of whether a question concerning representation exists that an election is needed to answer. For that reason, the Board has consistently sustained regional directors' decisions to defer resolving questions of individual employees' eligibility to vote until after an election (in which the disputed employees may cast challenged ballots). In *Northeast Iowa Telephone Co.,* 341 NLRB 670, 671 (2004), the Board characterized this procedure as the ''tried-and-true 'vote under challenge procedure.' '' See also *HeartShare Human Services of New York, Inc.,* 320 NLRB 1 (1995). The Eighth Circuit has stated that ''deferring the question of voter eligibility until after an election is an accepted NLRB practice.'' *Bituma Corp.* v. *NLRB,* 23 F.3d 1432, 1436 (8th Cir. 1994). Even when a regional director resolves such a dispute pre-election, the Board, when a request for review is filed, often defers review of the resolution, permitting the disputed individuals to vote subject to challenge. See, *e.g., Medlar Elec., Inc.,* 337 NLRB 796, 796 (2002); *Interstate Warehousing of Ohio, LLC,* 333 NLRB 682, 682–83 (2001); *American Standard, Inc.,* 237 NLRB 45, 45 (1978).

In *Barre-National, Inc.,* 316 NLRB 877 (1995), however, the Board considered whether a regional director had acted properly when he deferred *both* litigation and a decision concerning the eligibility of 24 line and group leaders (constituting eight to nine percent of the unit) until after an election, over the objection of the employer contending that the leaders were supervisors. Quoting both section 102.66(a) and 101.20(c) of the existing regulations, the Board held that the two sections ''entitle parties at [pre-election] hearings to present witnesses and documentary evidence in support of their positions.'' *Id.* at 878. For that reason, the Board held that the regional director had erred by deferring the taking of the employer's testimony until after the election. But the Board did not hold in *Barre-National* that the disputed issue had to be resolved before the regional director directed an election. In fact, the Board expressly noted, ''[O]ur ruling concerns only the entitlement to a preelection hearing, which is distinct from any claim of entitlement to a final Agency decision on any issue raised in such a hearing.'' *Id.* at 879 n. 9. The Board further noted that ''reviewing courts have held that there is no general requirement that the Board decide all voter eligibility issues prior to an election.'' *Id.*

3. Provision of a List of Eligible Voters

In elections conducted under Section 9 of the Act, there is no list of employees or potentially eligible voters generally available to interested parties other than the employer and, typically, an incumbent representative. The Board addressed this issue in *Excelsior Underwear, Inc.,* 156 NLRB 1236, 1239–40 (1966), where it held:

> [W]ithin 7 days after the Regional Director has approved a consent-election agreement * * * or after the Regional Director or the Board has directed an election * * *, the employer must file with the Regional Director an election eligibility list, containing the names and addresses of all the eligible voters. The Regional Director, in turn, shall make this information available to all parties in the case. Failure to comply with this requirement shall be grounds for setting aside the election whenever proper objections are filed.

Although several Justices of the Supreme Court expressed the view that the requirement to produce what has become known as an ''*Excelsior* list'' should have been imposed through rulemaking rather than adjudication, the Court upheld the substantive requirement in *NLRB* v. *Wyman-Gordon Co.,* 394 U.S. 759, 768 (1969).

In *Excelsior,* the Board explained the primary rationale for requiring production of an eligibility list:

> As a practical matter, an employer, through his possession of employee names and home addresses as well as his ability to communicate with employees on plant premises, is assured of the continuing opportunity to inform the entire electorate of his views with respect to union representation. On the other hand, without a list of employee names and addresses, a labor organization, whose organizers normally have no right of access to plant premises, has no method by which it can be certain of reaching all the employees with its arguments in favor of representation, and, as a result, employees are often completely unaware of that point of view. This is not, of course, to deny the existence of various means by which a party *might* be able to communicate with a substantial portion of the electorate even without possessing their names and addresses. It is rather to say what seems to us obvious—that the access of *all* employees to such communications can be insured only if all parties have the names and addresses of all the voters.

156 NLRB at 1240–41 (footnote omitted). The Supreme Court endorsed this rationale in *Wyman-Gordon,* 394 U.S. at 767, ''The disclosure requirement furthers this objective [to ensure the fair and free choice of bargaining representatives] by encouraging an informed employee electorate and by allowing unions the right of access to employees that management already possesses.''

The Board also articulated a second reason for requiring production of an eligibility list in *Excelsior:*

> The [voter] list, when made available, not infrequently contains the names of employees unknown to the union and even to its employee supporters. The reasons for this are, in large part, the same as those that make it difficult for a union to obtain, other than from the employer, the names of all employees; i.e., large plants with many employees unknown to their fellows, employees on layoff status, sick leave, military leave, etc. With little time (and no home addresses) with which to satisfy itself as to the eligibility of the ''unknowns,'' the union is forced either to challenge all those who appear at the polls whom it does not know or risk having ineligible employees vote. The effect of putting the union to this choice, we have found, is to increase the number of challenges, as well as the likelihood that the challenges will be determinative of the election, thus requiring investigation and resolution by the Regional Director or the Board. Prompt disclosure of employee names as well as addresses will, we are convinced, eliminate the necessity for challenges based solely on lack of knowledge as to the voter's identity. Furthermore, bona fide disputes between employer and union over voting eligibility will be more susceptible of settlement without recourse to the formal and time-consuming challenge procedures of the Board if such disputes come to light early in the election campaign rather than in the last few days before the election when the significance of a single vote is apt to loom large in the parties' calculations. Thus the requirement of prompt disclosure of employee names and addresses will further the public interest in the speedy resolution of questions of representation.

156 NLRB at 1242–43.

Since *Excelsior* was decided, almost 50 years ago, the Board has not significantly altered its requirements despite significant changes in communications technology, including that used in representation election campaigns, and identification of avoidable problems in administering the requirement, for example, delays in the regional offices' transmission of the eligibility list to the parties.

B. Evolution of the Board's Electronic Filing and Service Requirements

The Board's effort to promote expeditious case processing under the NLRA by utilizing advances in communications technology is nearly a decade old. The Board first began a pilot project in 2003, permitting the electronic filing of documents with the Agency.[24] Thereafter, the use and scope of electronic filing by parties to NLRB proceedings expanded significantly. By January 2009, more than 12,000 documents had been filed electronically with the Board and its regional offices.[25] The Board currently permits most documents in both unfair labor practice and representation proceedings to be filed electronically with only a limited number of expressly specified exceptions.[26] The NLRB public Web site sets out instructions for the Agency's E-filing procedures in order to facilitate their use, and the instructions ''strongly encourage parties or other persons to use the Agency's E-filing program.'' [27] However, included among documents that may not currently be filed electronically are representation petitions.[28]

In 2008, the Board initiated another pilot project to test the ability of the Agency to electronically issue its decisions and those of its administrative law judges.[29] Parties who register for electronic service of decisions in their cases receive an e-mail constituting formal notice of the decision and an electronic link to the decision. The NLRB public Web site sets out instructions for signing up for the Agency's electronic issuance program.[30]

In 2009, the Board revised its regulations to require that service of e-filed documents on other parties to a proceeding be effectuated by e-mail whenever possible, which aligned Board service procedures more closely with those in the federal courts, and acknowledged the widely accepted use of e-mail for legal and official communications.[31]

In 2010, the Board took further notice of the spread of electronic communications in its decision in *J. Piccini Flooring,* 356 NLRB No. 9 (2010), to require that respondents in unfair labor practice cases distribute remedial notices electronically when that is their customary means of communicating with employees. The Board recognized that the use of e-mail, internal and external Web sites, and other electronic communication tools, is now the norm for the transaction of business in many workplaces, among unions, and by the government and the public it serves. The Board concluded that its ''responsibility to adapt the Act to changing patterns of industrial life'' [32] required it to align its remedial requirements with ''the revolution in communications technology that has reshaped our economy and society.'' *J. Piccini Flooring,* slip op. at 4.

C. Purposes of the Proposed Amendments

The Board now proposes to revise its rules and regulations to better insure ''that employees' votes may be recorded accurately, efficiently and speedily'' and to further ''the Act's policy of expeditiously resolving questions concerning representation.'' [33]

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[24] See 74 FR 5618, 5619 (Jan. 30, 2009), revising § 102.114 of the Board's Rules and Regulations, corrected 74 FR 8214 (Feb. 24, 2009).

[25] *Id.,* 74 FR at 5619.

[26] See NLRB Rules and Regulations Section 102.114(i); *http://www.nlrb.gov,* under Cases & Decisions/File Case Documents/E-file.

[27] See *http://www.nlrb.gov,* under E-filing Rules.

[28] See *http://www.nlrb.gov,* under What Documents Can I E-file?

[29] See 74 FR at 5619.

[30] See *http://www.nlrb.gov,* under What is E-Service?

[31] See 74 FR 8214 (Feb. 24, 2009), correcting 74 FR 5618; NLRB Rules & Regulations § 102.114(a) and (i).

[32] *NLRB* v. *Weingarten,* 420 U.S. 251, 266 (1975).

[33] *NLRB* v. *A.J. Tower Co.,* 329 U.S. 324, 331 (1946); *Northeastern University,* 261 NLRB 1001, 1002 (1982).

The proposed amendments would remove unnecessary barriers to the fair and expeditious resolution of questions concerning representation. In addition to making the Board processes more efficient, the proposed amendments are intended to simplify the procedures, to increase transparency and uniformity across regions, and to provide parties with clearer guidance concerning the representation case procedure.

The proposed amendments would provide for more timely and complete disclosure of information needed by both the Board and the parties to promptly resolve matters in dispute. The proposed amendments are also intended to eliminate unnecessary litigation concerning issues that may be, and often are, rendered moot by election results. In addition, the proposed amendments would consolidate Board review of regional directors' determinations in representation cases in a single, post-election proceeding and would make review discretionary after an election as it currently is before an election. The Board anticipates that the proposed amendments would leave a higher percentage of final decisions about disputes arising out of representation proceedings with the Board's regional directors who are members of the career civil service. Finally, the proposed amendments are intended to modernize the Board's representation procedures, in particular, through use of electronic communications technology to speed communication among the parties, and between the parties and the Board, and to facilitate communication with voters.

Given the variation in the number and complexity of issues that may arise in a representation proceeding, the amendments do not establish inflexible time deadlines or mandate that elections be conducted a set number of days after the filing of a petition. Rather, the amendments seek to avoid unnecessary litigation and establish standard and fully transparent practices while leaving discretion with the regional directors to depart from those practices under special circumstances.

Consistent with Executive Order 13563, Improving Regulation and Regulatory Review, section 6(a) (January 18, 2011), the proposed amendments would eliminate redundant and outmoded regulations.[34] The proposed amendments would eliminate one entire section of the Board's current regulations and consolidate the regulations setting forth procedures under section 9 of the Act, currently spread across three separate parts of the regulations, into a single part. The Board anticipates that, if the proposed amendments are adopted, the cost of invoking and participating in the Board's representation case procedures would be reduced for parties, and public expenditure in administering section 9 of the Act would be similarly reduced.

While the proposed amendments are designed to eliminate unnecessary barriers to the speedy processing of representation cases, the proposed amendments, like previous congressional and administrative reforms aimed at expediting the conduct of elections, do not in any manner alter existing regulation of parties' campaign conduct or restrict any party's freedom of speech.

The Board invites comments on each of the proposed rule changes described below.[35]

D. Summary of Current Representation Case Procedures

Every year, thousands of election petitions are filed in NLRB regional offices by employees, unions, and employers to determine if employees wish to be represented by a labor organization for purposes of collective bargaining with their employer.[36] A lesser number are filed by employees to determine whether the Board should decertify an existing representative.[37] Under current procedures, the petitioner is not required to serve the petition on other interested parties. For example, a labor organization is not required to serve a petition through which it seeks to be certified as the representative of a unit of employees on the employees' employer. Rather, that task is imposed on the regional office. In addition, the petitioner is not required, at the time of filing, to supply evidence of the type customarily required by the Board to process the petition. For example, a labor organization is not required to file, along with its petition, evidence that a substantial number of employees support the petition (the ''showing of interest''). Rather, the petitioner is permitted to file such evidence within 48 hours of the filing of the petition.

After a petition is filed, the regional director serves the petition on the parties and also submits additional requests to the employer. The regional director serves on the employer a generic notice of employees' rights,[38] with a request that the employer post the notice, and a commerce questionnaire, seeking information relevant to the Board's jurisdiction to process the petition,[39] which the employer is requested to complete. The regional director also asks the employer to provide a list of the names of employees in the unit described in the petition, together with their job classifications, for the payroll period immediately preceding the filing of the petition. Finally, the regional director solicits the employer's position on the appropriateness of the unit described in the petition.

After the filing of a petition, Board agents conduct an ex parte, administrative investigation to determine if the petition is supported by the required form of showing. In the case of a petition seeking representation or seeking to decertify an existing representative, for example, this showing would be that 30 percent of employees in the unit support the petition.

Shortly after a petition is filed, the regional director serves a notice on the parties named in the petition setting a pre-election hearing. In many cases, the parties, often with Board agent assistance, are able to reach agreement regarding the composition of the unit and the date, time, place, and other mechanics of the election, thereby

[34] While the Executive Order is not binding on the Board as an independent agency, the Board has, as requested by the Office of Management and Budget, given ''consideration to all of its provisions.'' Office of Management and Budget, Memorandum for the Heads of Executive Departments and Agencies, and of Independent Regulatory Agencies: Executive Order 13563, ''Improving Regulation and Regulatory Review'' 11–12 (Feb. 2, 2011), *http://www.whitehouse.gov/omb/memoranda.* In regard to section 2(c) of the Order, concerning seeking the views of those who are likely to be affected prior to publication of a notice of proposed rulemaking, the Board determined that public participation would be more orderly and meaningful if it was based on the specific proposals described herein and thus the Board has provided for the comment and reply periods and public hearing described above.

[35] The Board has provided for an initial 60-day comment period followed by a 14-day reply period. In addition, the Board intends to issue a notice of public hearing to be held in Washington, DC on July 18–19 during the initial comment period in order to receive oral comments on the proposed amendments. The Board believes that all persons interested in the proposed amendments—including those best able to provide informed comment on the details of the Board's representation case procedures, the attorneys and other practitioners who regularly participate in representation proceedings—will have ample time and opportunities to do so within the two comment periods and at the public hearing.

[36] In 2010, 2,447 such petitions were filed. See Chart 9—Representation Elections (RC) and Chart 11—Employer petitioned Elections (RM), *http://www.nlrb.gov/chartsdata/petitions.*

[37] In 2010, 530 such petitions were filed. See Chart 10—Decertification Elections (RD), *http://www.nlrb.gov/chartsdata/petitions.*

[38] Form NLRB–5492, Notice to Employees.

[39] Form NLRB–5081.

eliminating the need for a hearing and a formal decision and direction of election by the regional director.[40] Parties may enter into three types of pre-election agreements: A ''consent-election agreement followed by a regional director's determination of representatives,'' providing for final resolution of post-election disputes by the regional director; a ''stipulated election-agreement followed by a Board determination,'' providing for resolution of post-election disputes by the Board; and a ''full consent-election agreement,'' providing for final resolution of both pre- and post-election disputes by the regional director.[41] In cases in which parties are unable to reach agreement, a Board agent conducts a hearing at which the parties may introduce evidence on issues including: (1) Whether the Board has jurisdiction to conduct an election; (2) whether there are any bars to an election in the form of existing contracts or prior elections; (3) whether the election is sought in an appropriate unit of employees; and (4) the eligibility of particular employees in the unit to vote. Parties can file briefs with the regional director within one week after the close of the hearing.

After the hearing's close, the regional director will issue a decision either dismissing the petition or directing an election in an appropriate unit. The regional director may defer the resolution of whether certain employees are eligible to vote until after the election, and those employees will be permitted to vote under challenge.

Parties have a right to request Board review of a regional director's decision and direction of election within 14 days after it issues. Neither the filing nor grant of a request for review operates as a stay of the direction of election unless the Board orders otherwise. If the Board does not rule on the request before the election, the ballots are impounded pending a Board ruling. Consistent with the Board's current Statements of Procedures, the regional director ''will normally not schedule an election until a date between the 25th and 30th day after the date of the decisions, to permit the Board to rule on any request for review which may be filed.'' [42]

Within seven days after the regional director's decision issues, the employer must file a list of employees in the bargaining unit and their home addresses with the regional director. The regional director, in turn, makes the list available to all other parties in order to allow all parties to communicate with eligible employees about the upcoming election and to reduce the necessity for election-day challenges based solely on the parties' lack of knowledge of voters' identities. The non-employer parties must have this list at least ten days before the date of the election unless they waive that right.

The regional director has discretion to set the dates, times, and location of the election. The regional director typically exercises that discretion after consultation with the parties and solicitation of their positions on the election details.

Once the regional director sets the dates, times, and locations of the election, the regional office prepares a notice of election to inform eligible voters of those details.[43] The regional director serves the notice on the employer, which is responsible for posting the notice in the workplace for at least three days before the election.

If a manual election is held, each party to the election may be represented at the polling site by an equal number of observers who are typically employees of the employer. Observers have the right to challenge the eligibility of any voter for cause, and the Board agent conducting the election must challenge any voter whose name is not on the eligibility list. Ballots of challenged voters, including any voters whose eligibility was disputed at the pre-election hearing but not resolved by the regional director, are segregated from the other ballots in a manner that will not disclose the voter's identity.

Representatives of all parties may choose to be present when ballots are counted. Elections are decided by a majority of votes cast. Challenges may be resolved by agreement before the tally. If the number of unresolved challenged ballots is insufficient to affect the results of an election in which employees voted to be represented, the unit placement of any individuals whose status was not resolved may be resolved by the parties in collective bargaining or determined by the Board if a petition for unit clarification is filed. If the number of unresolved challenged ballots is insufficient to affect the results of an election in which employees voted not to be represented, the results are certified unless objections are filed.

Within one week after the tally of ballots has been prepared, parties may file with the regional director objections to the conduct of the election or to conduct affecting the results of the election. A party filing objections has an additional week to file a summary of the evidence supporting the objections.

The regional director may initiate an investigation of any such objections and unresolved, potentially outcome-determinative challenges, and notice a hearing only if they raise substantial and material factual issues. If they do not, the regional director will issue a supplemental decision or a report disposing of the challenges or objections. If there are material factual issues that must be resolved, the regional director will notice a post-election hearing before a hearing officer to give the parties an opportunity to present evidence concerning the objections or challenges. After the hearing's close, the hearing officer will issue a report resolving any credibility issues and containing findings of fact and recommendations. Depending upon the type of election, a party may file exceptions to the hearing officer's report either with the regional director or the Board, whereupon the regional director or the Board will issue a decision. If the right is not waived in a pre-election agreement, a party may appeal a regional director's disposition of election objections or challenges by filing exceptions with the Board.

II. Authority

Section 6 of the NLRA, 29 U.S.C. 156, provides, ''The Board shall have authority from time to time to make, amend, and rescind, in the manner prescribed by subchapter II of chapter 5 of Title 5 [the Administrative Procedure Act, 5 U.S.C. 553], such rules and regulations as may be necessary to carry out the provisions of this Act.'' The Board interprets Section 6 as authorizing the proposed amendments to its existing rules.

The Board believes that the proposed amendments relate almost entirely to ''rules of agency organization, procedure or practice'' and are therefore exempt from the Administrative Procedure Act's notice and comment requirements under 5 U.S.C. 553(b)(A), but the Board has decided nevertheless to issue this Notice of Proposed Rulemaking and seek public comments.

III. Overview of the Amendments

Part 101, Subparts C–E

The Board's current regulations are divided into part 102, denominated Rules and Regulations, and part 101, denominated Statement of Procedures. Because the regulations in part 102 are procedural, however, the two sets of provisions governing representation

[40] In the last decade, between 86 and 92 percent of representation elections have been conducted pursuant to either a consent agreement or stipulation. NLRB Office of the General Counsel, Summaries of Operations (Fiscal Years 2002–2010).

[41] See 29 CFR 101.19.

[42] 29 CFR 101.21(d).

[43] Form NLRB–707 or Form NLRB–4910 (in the case of a mail ballot election).

proceedings in §§ 102.60–102.88 and 101.17–101.30 are almost entirely redundant. Describing the same representation procedures in two separate parts of the regulations may create confusion.

Section 101.1 states that part 101 is a statement of ''the general course and method by which the Board's functions are channeled and determined'' and is issued pursuant to 5 U.S.C. 552(a)(1)(B). The Board believes that such a description of procedures would better serve the statutory purpose of informing the public concerning Agency procedures and practices if it were incorporated into the Board's procedural rules in part 102. The proposed amendments would thus eliminate those sections of part 101 related to representation cases, §§ 101.17 through 101.30, and incorporate into part 102 the few provisions of current part 101 that are not redundant or superfluous.

A separate statement of ''the general course and method by which the Board's functions are channeled and determined'' in representation proceedings is also set forth in section I(D) above. To the extent any amendments are adopted by the Board, the preamble of the final rule will contain a statement of the general course and method by which the Board's functions will be channeled and determined under the amendments. Moreover, the Board will continue to publish and update its detailed Casehandling Manual, Part Two of which describes the Board's representation case procedures. The Manual is currently available on the Board's Web site.

Part 102, Subpart C—Procedure Under Section 9(c) of the Act for the Determination of Questions Concerning Representation of Employees and for Clarification of Bargaining Units and for Amendment of Certifications Under Section 9(b) of the Act

Sec. 102.60 Petitions

The proposed amendments would permit parties to file petitions electronically. In conformity with ordinary judicial and administrative practice, the amendments also require that the petitioner serve a copy of the petition on all other interested parties. For example, a labor organization filing a petition seeking to become the representative of a unit of employees is required to serve the petition on the employer of the employees. This will insure that the earliest possible notice of the pendency of a petition is given to all parties.

The proposed amendments would also require service of two additional documents that would be available to petitioners in the regional offices and on the Board's public Web site. The first document, which would substitute for and be an expanded version of the Board's Form 4812, would inform interested parties of their rights and obligations in relation to the representation proceeding. The second document the petitioner would serve along with the petition would be a Statement of Position form, which would substitute for NLRB form 5081, the Questionnaire on Commerce Information. The contents and purpose of the proposed Statement of Position form is described further below in relation to § 102.63.

Sec. 102.61 Contents of Petition for Certification; Contents of Petition for Decertification; Contents of Petition for Clarification of Bargaining Unit; Contents of Petition for Amendment of Certification

Section 102.61 describes the contents of the various forms of petitions that may be filed to initiate a representation proceeding under section 9 of the Act. The Board would continue to make each form of petition available at the Board's regional offices and on its Web site. The proposed amendments would add to the contents of the petitions in two respects. First, the revised petition would contain the allegation required in section 9. In the case of a petition seeking representation, for example, the petition would contain a statement that ''a substantial number of employees * * * wish to be represented for collective bargaining.'' 29 U.S.C. 159(c)(1)(a)(i). Second, the petitioner would be required to designate, in the revised petition, the individual who will serve as the petitioner's representative in the proceeding, including for purposes of service of papers.

The proposed amendments would also require that the petitioner file with the petition whatever form of evidence is an administrative predicate of the Board's processing of the petition rather than permitting an additional 48 hours after filing to supply the evidence. When filing a petition seeking to be certified as the representative of a unit of employees, for example, petitioners would be required simultaneously to file the showing of interest supporting the petition. The Board's preliminary view is that parties should not file petitions without whatever form of evidence is ordinarily necessary for the Board to process the petition. However, the proposed amendments are not intended to prevent a petitioner from supplementing its showing of interest, consistent with existing practice, so long as the supplemental filing is timely. Also consistent with existing practice, the amendments do not require that such a showing be served on other parties. The amendments are not intended to change the Board's longstanding policy of not permitting the adequacy of the showing of interest to be litigated. See, *e.g., Plains Cooperative Oil Mill,* 123 NLRB 1709, 1711 (1959) (''[T]he Board has long held that the sufficiency of a petitioner's showing of interest is an administrative matter not subject to litigation.''); *O.D. Jennings & Co.,* 68 NLRB 516 (1946). Nor are the proposed amendments intended to alter the Board's current internal standards for determining what constitutes an adequate showing of interest.[44]

The proposed amendments are not intended to permit or proscribe the use of electronic signatures to support a showing of interest under § 102.61(a)(12) and (c)(11) as well as under § 102.84. The Board continues to study the use of such signatures for these purposes. See Government Paperwork Elimination Act, Public Law 105–277 section 1704(2) (1998) (providing that Office of Management and Budget shall ensure that, commencing not later than five years after the date of enactment of the Act, executive agencies provide ''for the use and acceptance of electronic signatures, when practicable''); OMB, Implementation of the Government Paperwork Elimination Act, available at *http://www.whitehouse.gov/omb/fedreg_gpea2/;* Electronic Signatures in Global and National Commerce Act, Public Law 106–229 sections 104(b)(1) and (2) (2000). The Board specifically seeks comments on the question of whether the proposed regulations should expressly permit or proscribe the use of electronic signatures for these purposes.

Sec. 102.62 Election agreements; voter list

Existing § 102.62 describes the three types of agreements parties may enter into following the filing of a petition. The proposed amendments would not in any manner limit parties' ability to enter into such agreements, including the two forms of agreement that entirely eliminate the need for a pre-election hearing. In fact, the Board anticipates that the proposed amendments would facilitate parties' entry into these forms of election agreements through an

[44] See Casehandling Manual section 11023.1.

earlier and more complete identification of disputes and disclosure of relevant information. The proposed amendments explain the common designations used to refer to each type of agreement in current § 101.19 in order to more clearly inform the public what each form of agreement provides. The proposed amendments would revise the second type of agreement, described in § 102.62(b) (the so-called stipulated election agreement), to eliminate parties' ability to agree to have post-election disputes resolved by the Board and to provide instead that the parties may agree that Board review of a regional director's resolution of such disputes may be sought through a request for review. This is consistent with the changes proposed in §§ 102.65 and 102.67 eliminating the authority of regional directors to transfer cases to the Board at any time and making Board review of regional directors' disposition of post-election disputes discretionary in cases where the parties have not addressed the matter in a pre-election agreement.

The proposed amendments (in § 102.62 as well as in § 102.67(j)) would codify and revise the requirement created in *Excelsior Underwear, Inc.,* 156 NLRB 1236 (1966), and approved by the Supreme Court in *NLRB* v. *Wyman-Gordon Co.,* 394 U.S. 759, 768 (1969), for production and service of a list of eligible voters. The proposed amendments would require that both telephone numbers and, where available, e-mail addresses be included along with each unit employee's name and address on the eligibility list. The proposed amendments would further require that the list include each employee's work location, shift, and classification. The changes in the existing requirement for provision of a list of eligible voters embodied in the proposed amendments are intended to better advance the two objectives articulated by the Board in *Excelsior.*

The provision of only a physical address no longer serves the primary purpose of the *Excelsior* list. Communications technology and campaign communications have evolved far beyond the face-to-face conversation on the doorstep imagined by the Board in *Excelsior.* As Justice Kennedy observed in *Denver Area Educational Telecommunications Consortium, Inc.* v. *FTC,* 518 U.S. 727, 802–803 (1996) (Kennedy, J., dissenting):

> Minds are not changed in streets and parks as they once were. To an increasing degree, the most significant interchanges of ideas and shaping of public consciousness occur in mass and electronic media. The extent of public entitlement to participate in those means of communication may be changed as technologies change.

Similarly, in *J. Picini Flooring,* 356 NLRB No. 9 at 2–3 (2010) (footnotes omitted), the Board recently observed,

> While * * * traditional means of communication remain in use, email, postings on internal and external websites, and other electronic communication tools are overtaking, if they have not already overtaken, bulletin boards as the primary means of communicating a uniform message to employees and union members. Electronic communications are now the norm in many workplaces, and it is reasonable to expect that the number of employers communicating with their employees through electronic methods will continue to increase. Indeed, the Board and most other government agencies routinely and sometimes exclusively rely on electronic posting or email to communicate information to their employees. In short, ''[t]oday's workplace is becoming increasingly electronic.''

The same evolution is taking place in pre-election campaign communication. The Board's experience with campaigns preceding elections conducted under section 9 of the Act indicates that employers are, with increasing frequency, using e-mail to communicate with employees about the vote. See, *e.g., Humane Society for Seattle,* 356 NLRB No. 13, slip op. at 4 (2010) (''On September 27, the Employer's CEO, Brenda Barnette, sent an e-mail to employees asking that they consider whether ACOG was the way to make changes at SHS. On September 29, HR Director Leader e-mailed employees a link to a third-party article regarding 'KCACC Guild's petition and reasons the Guild would be bad for SHS.''); *Research Foundation of the State University of New York at Buffalo,* 355 NLRB No. 170, slip op. at 19 (2010) (''On January 12, Scuto sent the first in a series of e-mail's [sic] to all Employer postdoctoral associates concerning the Petitioner's efforts to form a Union at the Employer[,]. * * * explaining the Employer's position on unionization * * *.''); *Black Entertainment Television,* 2009 WL 1574462, at *1 (NLRB Div. of Judges June 5, 2009) (employer notified several employees by e-mail to attend a meeting in which senior vice-president spoke one-on-one with the employees regarding the election scheduled for the following day). For these reasons, the proposed rule would require that both telephone numbers and, where available, e-mail addresses be included on the *Excelsior* list.[45]

In addition, the list currently required under *Excelsior* does little to further the second purpose for requiring its production—to identify issues concerning eligibility and, if possible, to resolve them without the necessity of a challenge. In many cases, the names on the list are unknown to the parties. The parties may not know where the listed individuals work or what they do. Only through further factual investigation, for example, consulting other employees who may work with the listed, unknown employees or contacting the unknown employees themselves at their home addresses, can the parties potentially discover the facts needed to assess eligibility. It would further the purpose of narrowing the issues in dispute—and thereby avoid unnecessary challenges and litigation—if the list also contained work location, shift, and classification.

The proposed amendments would further require that the eligibility list be provided in electronic form unless the employer certifies that it does not possess the capacity to produce the list in the required form. In 1966, most employers maintained employee lists only on paper. Today, many, if not most, employers maintain electronic records. Yet when producing an *Excelsior* list, employers are still permitted to print out a copy of their electronic records and provide a paper list to the regional office which, in turn, mails or faxes a copy to the other parties. Requiring production of the list in electronic form would further both purposes of the *Excelsior* requirement.

The proposed amendments would require that the employer serve the eligibility list on the other parties electronically at the same time it is filed with the regional office. The Board's existing rule, as announced in *Excelsior,* requires only that the employer file the list with the regional director. 156 NLRB at 1240 (1966). *Excelsior* further provides that the regional director shall make the list available to all parties. It is the Board's experience in administering elections that this two-step process has caused needless administrative burden, avoidable delay in receipt of the list, and unnecessary litigation when the regional office, for a variety of reasons, has not promptly made the list available to all parties. See, *e.g., Special Citizens Futures*

[45] In *Trustees of Columbia University,* 350 NLRB 574, 576 (2007), the Board rejected an objection based on an employer's refusal to include e-mail addresses in the *Excelsior* list of employees on board a ship that was at sea for most of the pre-election period. In so doing, the Board held only that, ''given the Employer's undisputed compliance with its *Excelsior* obligations as they stood as of the date of the Union's request, we are unwilling, on the facts of this case, to characterize that compliance as objectionable conduct.'' *Id.* at 576.

Unlimited, 331 NLRB 160, 160–62 (2000); *Alcohol & Drug Dependency Services,* 326 NLRB 519, 520 (1998); *Red Carpet Bldg. Maintenance Corp.,* 263 NLRB 1285, 1286 (1982); *Sprayking, Inc.,* 226 NLRB 1044, 1044 (1976). If adopted, the proposed amendments would eliminate this unnecessary administrative burden—as well as potential source of delay and resulting litigation—by providing for direct service of the list by the employer on all other parties. The regional office would make the list available upon request to the parties.

The proposed amendments would also shorten the time for production of the eligibility list from the current seven days to two days, absent agreement of the parties to the contrary or extraordinary circumstances specified in the direction. The Board's preliminary view is that advances in electronic recordkeeping and retrieval, combined with the provision of a preliminary list as described below in relation to § 102.63, render the full seven-day period unnecessary. This conclusion is also supported by the fact that the median size of units ranged between 23 and 26 employees from 2001 to 2010.

Finally, the proposed amendments would also impose a restriction on the use of the eligibility list, barring parties from using it for any purposes other than the representation proceeding and related proceedings. The Board specifically seeks comments regarding what, if any, the appropriate sanction should be for a party's noncompliance with the restriction.

Sec. 102.63 Investigation of petition by regional director; notice of hearing; service of notice; Initial Notice to Employees of Election; Statement of Position form; withdrawal of notice

The proposed amendments provide that, absent special circumstances, the regional director would set the hearing to begin seven days after service of the notice of hearing. This provision reflects the current practice of some regions, but would make the practice explicit and uniform, thereby rendering Board procedures more transparent and predictable. Under the proposed amendments, parties served with a petition and description of representation procedures, as described above in relation to § 102.60, will thus be able to predict with a high degree of certainty when the hearing will commence even before service of the notice. The Board intends that the proposed amendments would be implemented consistent with the Board's decision in *Croft Metal, Inc.,* 337 NLRB 688, 688 (2002), requiring that, ''absent unusual circumstances or clear waiver by the parties,'' parties ''receive notice of a hearing not less than 5 days prior to the hearing, excluding intervening weekends and holidays.'' The proposed amendments would thus not require any party to prepare for a hearing in a shorter time than permitted under current law. Rather, as the Board held in *Croft Metal,* 337 NLRB at 688, ''By providing parties with at least 5 working days' notice, we make certain that parties to representation cases avoid the Hobson's choice of either proceeding unprepared on short notice or refusing to proceed at all.'' The Board specifically seeks comments on the feasibility and fairness of this time period and all other such periods proposed in this Notice as well as the wording and scope of the exceptions thereto.

The proposed amendments provide that, with the notice of hearing, the regional director would serve a revised version of the Board's Form 5492, currently headed Notice to Employees. Under the proposed amendments, the revised form would bear the heading Initial Notice to Employees of Election, would specify that a petition has been filed as well as the type of petition, the proposed unit, and the name of the petitioner, and would briefly describe the procedures that will follow. The Board anticipates that the Initial Notice would also provide employees with the regional office's Web site address, through which they can obtain further information about the processing of the petition, including obtaining a copy of any direction of election and Final Notice to Employees of Election as soon as they issue. Employers would be required to post the revised Initial Notice to Employees of Election unlike current Form 5492.

The proposed amendments further provide that the regional director would serve the petition, the description of procedures in representation cases, and the Statement of Position form on all non-petitioning parties.

The proposed amendments would further require that the regional director specify in the notice of hearing the due date for Statements of Position. The Statements of Position would be due no later than the date of the hearing. In relation to small units, the regional director may choose to make the Statements of Position due on the date of the hearing and they may be completed at that time with the assistance of the hearing officer.

The Statement of Position form would replace NLRB Form 5081, the Questionnaire on Commerce Information. Under the proposed rules, its completion would be mandatory only insofar as failure to state a position would preclude a party from raising certain issues and participating in their litigation. The statement of position requirement is modeled on the mandatory disclosures described in Fed. R. Civ. P. 26(a) as well as on contention interrogatories commonly propounded in civil litigation.

The Board anticipates that early receipt of the Statement of Position form will assist parties in identifying issues that must be resolved at a pre-election hearing and thereby facilitate entry into election agreements. Parties who enter into one of the forms of election agreement described in § 102.62 would not be required to complete a Statement of Position under the proposed amendments.

The Statement of Position form would solicit the parties' position on the Board's jurisdiction to process the petition; the appropriateness of the petitioned-for unit; any proposed exclusions from the petitioned-for unit; the existence of any bar to the election; the type, dates, times, and location of the election; and any other issues that a party intends to raise at hearing. In those cases in which a party takes the position that the proposed unit is not an appropriate unit, the party would also be required to state the basis of the contention and identify the most similar unit it concedes is appropriate.[46] In those cases in which a party intends to contest at the pre-election hearing the eligibility of individuals occupying classifications in the proposed unit, the party would be required to both identify the individuals (by name and classification) and state the basis of the proposed exclusion, for example, because the identified individuals are supervisors. Finally, parallel to the amendment to the contents of petitions described in relation to § 102.61 above, the non-petitioning parties would be required to designate, in their Statement of Position, the individual who will serve as the party's representative in the proceeding, including for service of papers.

The Board believes that the Statement of Position form would ask parties to do no more than they currently do in preparing for a pre-election hearing. In addition, the Board's preliminary belief is that, by guiding such preparation, the proposed Statement of Position form

[46] This requirement would codify parties' existing practice where they contend that the petitioned-for unit is not appropriate because the smallest appropriate unit includes additional classifications or facilities. See, *e.g., Westinghouse Electric Corp.,* 137 NLRB 332 (1962).

would reduce the time and other resources expended in preparing to participate in representation proceedings.

In *Bennett Industries, Inc.,* 313 NLRB 1363, 1363 (1994), the Board observed, ''[I]n order to effectuate the purposes of the Act through expeditiously providing for a representation election, the Board should seek to narrow the issues and limit its investigation to areas in dispute.'' The Board's regional offices currently attempt to identify and narrow the issues through a number of procedures. In some cases, regions will conduct pre-hearing conferences either face-to-face or by telephone in an effort to identify and narrow the issues in dispute. Further, section 11217 of the Casehandling Manual provides, ''Prior to the presentation of evidence or witnesses, parties to the hearing should succinctly state on the record their positions as to the issues to be heard.'' The proposed amendments would incorporate the principles underlying these commendable practices, but would give all parties clear, advance notice of their obligations, both in the rules themselves and in the statement of procedures and Statement of Position form. The amendments are not intended to preclude any other formal or informal methods used by the regional offices to identify and narrow the issues in dispute prior to or at pre-election hearings.

The proposed amendments provide that, as part of its Statement of Position, the employer would be required to provide a list of all individuals employed by the employer in the petitioned-for unit. The list would include the same information described above in relation to § 102.62 except that the list served on other parties would not include contact information.

As explained above in section I(A)(3) and in relation to § 102.62, a central purpose of requiring the employer to prepare and file an eligibility list is to insure that all parties have access to the information they need to evaluate whether individuals should be in the unit and are otherwise eligible to vote, so that the parties can attempt to resolve disputes concerning eligibility rather than prolong them ''based solely on lack of knowledge.'' *Excelsior,* 156 NLRB at 1243. The Board further observed in *Excelsior* that ''bona fide disputes between employer and union over voting eligibility will be more susceptible of settlement without recourse to the formal and time-consuming challenge procedures of the Board if such disputes come to light early in the election campaign rather than in the last few days before the election.'' But that purpose is not well served by provision of the list of eligible voters seven days after a decision and direction of election. It is prior to and during the hearing that the parties are most actively engaged in attempting to resolve such disputes. For this reason, the proposed amendments would require filing and service of a list of individuals providing services to the employer in the petitioned-for unit by a date no later than the opening of the pre-election hearing.

For the same reasons, the proposed amendments further provide that, if the employer contends that the petitioned-for unit is not appropriate, the employer also would be required to file and serve a similar list of individuals in the most similar unit that the employer concedes is appropriate.

Under the proposed amendments, the list filed with the regional office, but not the list served on other parties, would contain available e-mail addresses, telephone numbers, and home addresses. The regional office could then use this additional information to begin preparing the electronic distribution of the Final Notice of Election discussed below in relation to § 102.67.

Sec. 102.64 Conduct of Hearing

The proposed amendments to § 102.64 are intended to insure that the hearing is conducted efficiently and is no longer than necessary to serve the statutory purpose of determining if there is a question concerning representation. Congress instructed the Board to conduct a pre-election hearing to determine if there is a question concerning representation that should be resolved through an election. But Congress did not intend the hearing to be used by any party to delay the conduct of such an election. The proposed amendments would make clear that, ordinarily, resolution of disputes concerning the eligibility or inclusion of individual employees is not necessary in order to determine if a question of representation exists and, therefore, that such disputes will be resolved, if necessary, post-election. The proposed amendments would also make clear that the duty of the hearing officers is to create an evidentiary record concerning only genuine disputes as to material facts. Finally, the proposed amendments would provide that the hearing shall continue from day to day until completed absent extraordinary circumstances.

Sec. 102.65 Motions; Interventions

Consistent with the effort to avoid piecemeal appeal to the Board, as discussed below in relation to § 102.67, the proposed amendments to § 102.65 would narrow the circumstances under which a request for special permission to appeal will be granted. The proposed amendments provide that such an appeal would only be granted under extraordinary circumstances when it appears that the issue will otherwise evade review. To further discourage piecemeal appeal, the amendments provide that a party need not seek special permission to appeal in order to preserve an issue for review post-election. Finally, consistent with current practice, the amendments provide that neither the filing of a request for special permission to appeal nor the grant of such a request will stay an election or any other action or require impounding of ballots unless specifically ordered by the Board.

The proposed amendments provide that any intervenors, like the original non-petitioning parties, would be required to file or make a Statement of Position.

The proposed amendments also make clear that neither a regional director nor the Board will automatically delay any decision or action during the time permitted for filing motions for reconsideration, rehearing, and to reopen the record.

Sec. 102.66 Introduction of Evidence; Rights of Parties at Hearing; Subpoenas

The proposed amendments to § 102.66 are intended to limit the evidence offered at hearings to that evidence which is relevant to a genuine dispute as to a fact material to an issue in dispute. The amendments would thus give parties the right to introduce evidence ''relevant to any genuine dispute as to any material fact.'' This standard was derived from Rule 56 of the Federal Rules of Civil Procedure. The proposed amendments would not prevent any party from presenting evidence concerning any relevant issue if there is a genuine dispute as to any material fact. In other words, the proposed amendments would accord parties full due process of law consistent with that accorded in the federal courts.

The amendments would further describe a process to be followed by the hearing officer to identify issues in dispute and determine if there are genuine disputes as to facts material to those issues. The hearing officer would open the hearing by reviewing, or assisting the non-petitioning parties to

make, Statements of Position. The petitioner would then be required to respond to any issues raised in the non-petitioning parties' Statements of Position, thereby joining the issues. No party would be permitted to offer evidence or cross-examine witnesses concerning an issue it did not raise in its Statement of Position or did not join in response to another party's Statement of Position. However, any party would be permitted to present evidence as to statutory jurisdiction,[47] and the petitioner would be permitted to present evidence as to the appropriateness of the unit if the nonpetitioning parties decline to take a position on that issue. In addition, the hearing officer would retain discretion to permit parties to amend their Statements of Position and responses for good cause, such as newly discovered evidence.

Consistent with the amendment's intent to defer both litigation and consideration of disputes concerning the eligibility or inclusion of individual employees until after the election, no party would be precluded from challenging the eligibility or inclusion of any voter during the election on the grounds that no party raised the issue in a Statement of Position or response thereto.

The proposed amendments would implement the decision in *Bennett Industries, Inc.,* 313 NLRB 1363 (1994). The proposed amendments would also be consistent with *Allen Health Care Services,* 332 NLRB 1308 (2000), in which the Board held that even when an employer refuses to take a position on the appropriateness of a petitioned-for unit, the regional director must nevertheless take evidence on the issue unless the unit is presumptively appropriate. The proposed amendments would thus permit the petitioner to offer evidence in such circumstances and merely preclude non-petitioners, which have refused to take a position on the issue, from offering evidence or cross-examining witnesses.

Consistent with both *Bennett Industries* and *Allen Health Care*, the proposed amendments would preclude any party from subsequently raising an issue or offering evidence or cross-examining witnesses at the pre-election hearing related to an issue (other than statutory jurisdiction) it did not raise or join in a Statement of Position or response thereto. In the case of exclusions from the proposed unit, for example, if no party timely asserts that an individual should be excluded, the Board would include the individual subject to challenge during the election, as explained above. If no party objects to a proposed exclusion, the Board would exclude the individual. In relation to the appropriateness of the unit, if all parties agree the unit is appropriate, the Board would so find unless it appears on its face to be a statutorily inappropriate unit or to be inconsistent with settled Board policy. If any party refuses to take a position on the appropriateness of the unit, that party would be precluded from contesting the appropriateness and offering evidence relating to the appropriateness of the unit. Such preclusion is consistent with existing precedent and clarifies parties' rights under *Allen Health Care.*

Under the proposed amendments, after the issues are properly joined, the hearing officer would require the parties to make an offer of proof concerning any relevant issue in dispute and would not proceed to take evidence unless the parties' offers create a genuine issue of material fact. An offer of proof may take the form of an oral or written statement of the party or its counsel identifying the witnesses it would call to testify and summarizing their testimony. The requirement of an offer of proof is thus similar to that which exists under current procedures for a party filing objections post-election.[48] The requirement is also consistent with existing practice in relation to a presumptively appropriate unit. See, *e.g., Laurel Associates, Inc.,* 325 NLRB 603 (1998); *Mariah, Inc.,* 322 NLRB 586, 587 (1996). The proposed amendments thus adopt standard practice in the federal and state courts and before other agencies. See, *e.g.,* Fed. R. Civ. P. 56. The proposed amendments rest on the proposition that, if no disputed issues are identified or there are no disputed facts material to such issues, there is no need for an evidentiary hearing.

The Board's preliminary view is that ''an appropriate hearing'' does not mean an evidentiary hearing when either no issues are in dispute or no party has been able to make an offer of proof creating a genuine dispute as to any material fact. As Judge Learned Hand observed in 1949,

> Neither the statute, nor the Constitution, gives a hearing where there is no issue to decide * * *. The Constitution protects procedural regularity, not as an end in itself, but as a means of defending substantive interests. Every summary judgment denies a trial upon issues formally valid. Where, as here, the evidence on one side is unanswerable, and the other side offers nothing to match or qualify it, the denial of a trial invades no constitutional privilege. These considerations are particularly appropriate when we consider that the Board must conduct its duties in a summary way; not, we hasten to add, without observing all the essentials of fair administration, but with as much dispatch as is consistent with those.

Fay v. *Douds,* 172 F.2d 720, 725 (2d Cir. 1949).[49]

The common type of joinder of issues and offer-of-proof procedures set forth in the proposed amendments, which parallel even more common pleading and summary judgment procedures in the federal and state courts, are fully consistent with the statutory requirement of ''an appropriate hearing'' and all parties' rights to due process of law.

The proposed amendments would make clear that, although the Statement of Position form asks the non-petitioning parties to state their positions on the type, dates, times, and location of the election, and the eligibility period, and that the hearing officer should solicit all parties' positions on these issues, consistent with existing practice, the resolution of these issues remains within the discretion of the regional director, and the hearing officer shall not permit them to be litigated.

The proposed amendments would provide that, if, at any time during the hearing, the hearing officer determines that the only genuine issues remaining in dispute concern the eligibility or inclusion of individuals who would constitute less than 20 percent of the unit if they were found to be eligible to vote, the hearing officer will close the hearing.

Congress specified that a hearing take place before an election in order to insure that the Board determine that a question concerning representation exists prior to directing that an election

[47] Under the proposed amendments, the Board will continue its longstanding practice of presuming that an employer satisfies the Board's discretionary jurisdictional standards when the employer refuses to voluntarily provide information requested by the Board in order to apply those standards. See, *e.g., Seaboard Warehouse Terminals, Inc.,* 123 NLRB 378, 382–83 (1959); *Tropicana Products, Inc.,* 122 NLRB 121, 123–24 (1958).

[48] See Casehandling Manual section 1132.6 (''In addition to identifying the nature of the misconduct on which the objections are based, this submission should include a list of the witnesses and a brief description of the testimony of each.'')

[49] Although Judge Hand's analysis of the issue discussed in the text remains sound, the jurisdictional basis for *Fay* being heard in federal court prior to a final order in an unfair labor practice case has been ''effectively discarded by all circuits'' in subsequent decisions. Robert A. Gorman & Matthew W. Finkin, Labor Law: Unionization and Collective Bargaining § 4.11 (2d ed. 2004). See, *e.g., NLRB* v. *Interstate Dress Carriers, Inc.,* 610 F.2d 99, 107 (3d Cir. 1979); *Squillacote* v. *International Bhd. of Teamsters, Local 344,* 561 F.2d 31, 39 (7th Cir. 1977) (collecting cases).

be held in order to resolve the question. Thus, Section 9(c) provides that, after the filing of a petition,

> the Board shall investigate such petition and if it has reasonable cause to believe that a question of representation affecting commerce exists, it shall provide for an appropriate hearing upon due notice. * * * If the Board finds upon the record of such hearing that such a question of representation exists, it shall direct an election by secret ballot and shall certify the results thereof.

Congress did not, however, direct that every disputed issue related to the conduct of an election be litigated in the pre-election hearing or resolved prior to the conduct of the election.

Litigation and resolution of individual eligibility issues prior to elections is not the norm within our political system. In Board-supervised elections, it often results in unnecessary litigation and a waste of administrative resources as the eligibility of potential voters is litigated and decided even when their votes end up not affecting the outcome of the election. If a majority of employees vote against representation, even assuming all the disputed votes were cast in favor of representation, the disputed eligibility questions become moot. If, on the other hand, a majority of employees choose to be represented, even assuming all the disputed votes were cast against representation, the Board's experience suggests that the parties are often able to resolve the resulting unit placement questions in the course of bargaining and, if they cannot do so, either party may file a unit clarification petition to bring the issue back before the Board.[50] As the Eighth Circuit observed, ''The NLRB's practice of deferring the eligibility decision saves agency resources for those cases in which eligibility actually becomes an issue.'' *Bituma Corp.* v. *NLRB,* 23 F.3d 1432, 1436 (8th Cir. 1994). The Sixth Circuit similarly found that ''[s]uch a practice enables the Board to conduct an immediate election.'' *Medical Center at Bowling Green* v. *NLRB,* 712 F.2d 1091, 1093 (6th Cir. 1983).

The proposed revision of this section of the rules together with the elimination of section 101.20(c) removes the basis for the Board's holding in *Barre-National, Inc.,* 316 NLRB 877 (1995), that the hearing officer must permit full litigation of all eligibility issues in dispute prior to the direction of an election, absent consent of all parties to defer litigation of the issues. Congress specified that a hearing must be held to determine if ''a question concerning representation exists.'' Adjudication of the eligibility of the 24 individuals at issue in *Barre-National* was not necessary to determine whether a question concerning representation existed. Moreover, the Board did not hold in *Barre-National* that the disputed issue had to be resolved before the regional director directed and conducted an election. In fact, the Board expressly noted, ''our ruling concerns only the entitlement to a preelection hearing, which is distinct from any claim of entitlement to a final agency decision on any issue raised in such a hearing.'' *Id.* at 878 n. 9. The Board further noted that ''reviewing courts have held that there is no general requirement that the Board decide all voter eligibility issues prior to an election.'' *Id.* As observed above, the Board has frequently deferred final adjudication of such issues until after election, permitting disputed individuals to vote subject to challenge. Thus, the Board's holding in *Barre-National* required that an evidentiary hearing be held on the eligibility issue, potentially delaying the conduct of the election for a significant period of time, but the Board both in that case and in many others has permitted resolution of the issue to be deferred until after the election. Such an outcome serves no apparent purpose. Therefore, the proposed amendments would revise the regulations that formed the basis of the holding in *Barre-National* to permit deferral of both litigation and resolution of disputes that need not be resolved in order to determine that a question of representation exists.

The unit's scope must be established and found to be appropriate prior to the election. But the Board is not required to and should not decide all questions concerning the eligibility or inclusion of individual employees prior to an election. The Board's preliminary view is that deferring both the litigation and resolution of eligibility and inclusion questions affecting no more than 20 percent of eligible voters represents a reasonable balance of the public's and parties' interest in prompt resolution of questions concerning representation and employees' interest in knowing precisely who will be in the unit should they choose to be represented.

The proposed amendments are consistent with, but seek to improve, the Board's current practice concerning post-election rulings on eligibility and inclusion. In a variety of circumstances, most typically when the Board has granted a pre-election request for review concerning the scope of the unit or employee eligibility, but not ruled on the merits until after the election, the Board has addressed the question of when a post-election change in the unit described in the notice of election requires a new election. The Board has uniformly held that a change representing no more than 20 percent of the unit does not require a new election. See, *e.g., Morgan Manor Nursing and Rehabilitation Center,* 319 NLRB 552 (1995) (20 percent); *Toledo Hospital,* 315 NLRB 594 (1994) (19.5 percent). In *Morgan Manor,* the Board stated that ''the exclusion of one classification from a facilitywide service and maintenance unit comprised of employees in nine other specifically named classifications, represents a numerical change which we * * * do not view as signifying a sufficient change in unit size to warrant setting aside of the election.'' 319 NLRB at 553. Similarly, in *Toledo Hospital,* the Board found, ''We do not view the change in the size of the unit here (19.5 percent * * *) as signifying a sufficiently significant change in character and scope to warrant setting aside the election.'' 315 NLRB at 594. In a small number of cases,[51] courts of appeals have reversed the Board's conclusion that a new election was not necessary when the size of the unit was altered by less than 20 percent.[52] These courts have based their holdings on the particular nature of the change in the unit, concluding that it significantly altered the scope or character of the original unit. More importantly, these courts found that, by informing employees that they were voting to be represented in one unit and then changing the scope and character of the unit after the election, the Board was ''misleading the voters as to the scope of the unit.'' *NLRB* v. *Lorimar Productions, Inc.,* 771 F.2d 1294, 1302 (9th Cir. 1985) (involving approximately 35 percent reduction in size of unit); see also *NLRB* v. *Beverly Health and Rehabilitation Services,,* 120 F.3d 262 (4th Cir. 1977) (per curiam) (unpublished) (''Where employees are led to believe that they are voting on a particular bargaining unit and that bargaining unit is subsequently modified post-election, such that the bargaining unit, as modified, is fundamentally different in scope or

[50] See *New York Law Publishing Co.,* 326 NLRB No. 93, slip op. at 2 (2001) (''The parties may agree through the course of collective bargaining on whether the classification should be included or excluded. Alternatively, in the absence of such an agreement, the matter can be resolved in a timely invoked unit clarification petition.'')

[51] The Board has identified only two such cases, cited in the following footnote.

[52] See *NLRB* v. *Beverly Health and Rehabilitation Services,* 120 F.3d 262 (4th Cir. 1997) (per curiam) (unpublished) (reversing *Morgan Manor,* cited in text, involving a 20 percent reduction in size of unit); *NLRB* v. *Parsons School of Design,* 793 F.2d 503 (2d Cir. 1986) (involving a less than 10 percent reduction in size of unit).

character * * *, the employees have effectively been denied the right to make an informed choice in the representation election.'')

The Board's preliminary view is that adoption of a bright-line numerical rule requiring that questions concerning the eligibility or inclusion of individuals constituting no more than 20 percent of all potentially eligible voters be litigated and resolved, if necessary, post-election, best serves the interests of the parties and employees as well as the public interest in efficient administration of the representation case process.[53] In order to insure that prospective voters are in no way misled as to the scope of the unit, under the proposed amendments, if resolution of eligibility or inclusion disputes is deferred, the Final Notice to Employees of Election would so inform employees (including an explanation of how the dispute will be resolved) and the disputed employees would be permitted to vote subject to challenge as explained below in relation to § 102.67.

Consistent with existing practice, the proposed amendments also provide that a party that has been served with a subpoena may be required to file or orally present a motion to quash prior to the five days provided in section 11(1) of the Act. Both the Board and federal courts have construed the five days provided in the Act as a maximum, not a minimum. The Casehandling Manual provides:

> There is case authority which holds that the 5-day period is a maximum and not a minimum. Absent a showing of prejudice, the subpoenaed party may be required to file and argue its petition to revoke and, if ordered by the Administrative Law Judge or hearing officer, produce subpoenaed testimony and documents at hearing in less than 5 days from receipt of the subpoena. See *Packaging Techniques, Inc.,* 317 NLRB 1252, 1253–54 (1995) and *NLRB* v. *Strickland,* 220 F.Supp. 661, 665–66 (D.C.W. Tenn., 1962), affd. 321 F.2d 811, 813 (6th Cir. 1963).

Section 11782.4; see also *Brennan's French Restaurant,* 129 NLRB 52, 54 n.2 (1960) (judge's ruling found moot by Board). The proposed amendments would codify existing practice vesting discretion in the hearing office to determine how much time a party served with a subpoena should be accorded to move to quash up to the statutory maximum of five days. As the judge reasoned in *Packaging Techniques,* 317 NLRB at 1254, ''the case law suggests a common sense application of the rule.''

Finally, the proposed amendments provide that at the close of the hearing, parties would be permitted to make oral arguments on the record. Parties would be permitted to file briefs only with the permission of the hearing officer and within the time permitted by and subject to any other limitations imposed by the hearing officer. Given the recurring and often uncomplicated legal and factual issues arising in pre-election hearings, it is the Board's preliminary view that briefs are not needed in every case to permit the parties to fully and fairly present their positions or to facilitate prompt and accurate decisions.

Sec. 102.67 Proceedings Before the Regional Director; Further Hearing; Action by the Regional Director; Review of Action by the Regional Director; Statement in Opposition To Appeal; Final Notice of Election; Voter List

Consistent with the proposed amendment to § 102.66, the proposed amendments to § 102.67 would provide that if the regional director finds at any time that the only issues remaining in dispute concern the eligibility or inclusion of employees who would constitute less than 20 percent of the unit if they were found to be eligible to vote, the regional director shall direct that those individuals be permitted to vote subject to challenge. The proposed amendments would further provide that the Final Notice to Employees of Election shall explain that such individuals are being permitted to vote subject to challenge and the procedures through which their eligibility will be resolved.

The proposed amendments would give the regional director discretion to issue a direction of election with a decision to follow no later than the time of the tally of votes. Because the proposed amendments would defer the parties' right to request Board review of pre-election rulings until after the election, in order to avoid delaying the conduct of the election, regional directors may exercise their discretion to defer issuance of the decision up to the time of the tally without prejudice to any party.

Because the parties will have fully stated their positions on the type, dates, times, and locations of the election either in their Statements of Position or at the hearing, under the proposed amendments the regional director would address these election details in the direction of election and issue the Final Notice to Employees of Election with the direction. Consistent with both the statutory purpose for conducting elections and existing practice, the proposed amendments would provide that the regional director shall set the election for the earliest date practicable.

Both the decision and direction of election and the Final Notice to Employees of Election would be electronically transmitted to all parties when they have provided e-mail addresses to the regional office. When the parties have provided e-mail addresses of affected employees, the regional office would also transmit the notice electronically to those employees.[54] In addition, the employer would be required to post the Final Notice to Employees of Election in those places where it customarily posts notices to employees as well as electronically if the employer customarily uses electronic means to communicate with its employees. Because of the potential unfairness of conclusively presuming that the employer received the notice if it does not inform the region to the contrary within five work days, the proposed amendments would also eliminate the provision in § 103.20 creating such a conclusive presumption.

Because of the provision of a mandatory and more detailed initial notice of election, as described in relation to § 102.60 above, for manual and electronic posting of the final notice by employers, and for electronic transmission of the final notice of election to individual, eligible voters, in all cases where such notice is feasible, the proposed rules would also reduce the minimum time between the posting of the final notice and the election from three to two work days.

The Board anticipates that continuing advances in electronic communications and continuing expanded use of e-mail may, in the near future, enable regional offices in virtually all cases to transmit the final notice of election directly to all eligible voters, rendering employer posting of the final notice of election unnecessary. The Board similarly anticipates that the proposed amendments' adoption of dual notice procedures will be an interim measure. During this interim period, while the employer remains obligated to post the

[53] The Board has permitted regional directors to defer resolution of the eligibility of an even higher percentage of potential voters. See, *e.g., Northeast Iowa Telephone,* 341 NLRB 670, 671 (2004) (''While we recognize that allowing 25 percent of the electorate to vote subject to challenge is not optimal, the Employer's opportunity to raise its supervisory issues remains preserved through appropriate challenges and objections to the election or through a subsequent unit clarification petition.'')

[54] The proposed rules provide in §§ 102.62, 102.63, and 102.67 that both the preliminary and final eligibility lists include telephone numbers as well as e-mail addresses (when available) both to facilitate use of the final list for the purposes described in *Excelsior* and to permit the regions potentially to test the use of automated phone calls for the purpose of providing prompt notice of the election to each eligible voter.

final notice of election, the Board does not intend that the failure of a regional office to provide electronic notice to any eligible voter would be the basis for overturning the results of an election under the proposed amendments.

The proposed amendments would make the same changes in the form, content, and service of the list of eligible voters that the employer must file after a direction of election as were described above in relation to § 102.62 after entry into any form of consent or stipulated election agreement. In addition, because of advances in recordkeeping technology and because in most cases the employer will have provided a preliminary list of employees in the proposed or alternative units as described in relation to § 102.63 above, the proposed amendments would also reduce the time during which the list must be filed and served from seven days to two work days. Consistent with existing practice, reflected in *Mod Interiors, Inc.,* 324 NLRB 164 (1997), and Casehandling Manual section 11302.1, an election shall not be scheduled for a date earlier than ten days after the date by which the eligibility list must be filed and served, unless this requirement is waived by the petitioner and any other parties whose names will appear on the ballot.

The proposed amendments would eliminate the regional director's authority to transfer a case at any time to the Board for decision. This authority has rarely been used and, when it has been used, has led to extended delays in the disposition of petitions. See, *e.g., Centurion Auto Transport, Inc.,* 329 NLRB 394 (1999) (transferred December 1994, decided September 1999); *Roadway Package System, Inc.,* 326 NLRB 842 (1998) (transferred May 1995, decided August 1998); *PECO Energy Co.,* 322 NLRB 1074 (1997) (transferred Sept 1995, decided February 1997); *Johnson Controls, Inc.,* 322 NLRB 669 (1996) (transferred June 1994, decided December 1996).

As under the current rules, if the regional director dismisses the petition, parties would be permitted to file a request for review with the Board. If the regional director directs an election, however, the proposed amendments would defer all parties' right to request Board review until after the election. The proposed amendments would retain the provisions for a request for special permission to appeal a determination by the regional director, modified as described above in relation to § 102.65 above.

The Board's current Statements of Procedures provide that elections ''normally'' are delayed for a period of at least 25 days after the regional director directs that an election should be conducted, in order to provide the parties an opportunity to request Board review of the regional director's determinations.

> The parties have the right to request review of any final decision of the Regional Director, within the times set forth in the Board's Rules and Regulations, on one or more of the grounds specified therein. Any such request for review must be a self-contained document permitting the Board to rule on the basis of its contents without the necessity of recourse to the record, and must meet the other requirements of the Board's Rules and Regulations as to its contents. The Regional Director's action is not stayed by the filing of such a request or the granting of review, unless otherwise ordered by the Board. Thus, the Regional Director may proceed immediately to make any necessary arrangements for an election, including the issuance of a notice of election. However, unless a waiver is filed, the Director will normally not schedule an election until a date between the 25th and 30th days after the date of the decision, to permit the Board to rule on any request for review which may be filed.

29 CFR 101.21(d).

Thus, while the rules provide for discretionary review and expressly provide that requesting such review shall not operate as a stay of the election, the Statements of Procedures suggest that there should normally be a waiting period of 25–30 days. This is the case even though such requests are filed in a small percentage of cases, are granted in an even smaller percentage,[55] and result in orders staying the conduct of elections in virtually no cases at all. For these reasons, such a waiting period appears to serve little purpose even under the existing rules permitting a pre-election request for review.

The proposed amendments would eliminate the pre-election request for review and the accompanying waiting period. All pre-election rulings would remain subject to review post-election if they have not been rendered moot.

The Board anticipates that the proposed amendments would eliminate unnecessary litigation concerning issues that may be and often are rendered moot by the election results and thereby reduce the expense of participating in representation proceedings for the parties as well as the government. Similarly, by consolidating all Board review post-election, the proposed rules would relieve parties of the burden of petitioning for pre-election review in order to preserve issues that may be rendered moot by the election results and, even if that is not the case, would allow parties to raise all issues in a single petition and thereby preserve both private and public resources. In other words, the Board anticipates that the proposed amendments would not simply shift litigation from before to after elections, but would significantly reduce the total amount of litigation.

Section 102.68 Record; What Constitutes; Transmission to Board

The proposed amendments to this section would conform its contents to the amendments to other sections.

Sec. 102.69 Election Procedure; Tally of Ballots; Objections; Requests for Review of Directions of Elections, Hearings; Hearing Officer Reports on Objections and Challenges; Exceptions to Hearing Officer Reports; Requests for Review of Regional Director Reports or Decisions in Stipulated or Directed Elections

The proposed amendments to § 102.69 would maintain the current time period (seven days after the tally) for the filing of objections to the conduct of the election or to conduct affecting the results of the election. The current rules provide a filing party with an additional seven days to file an offer of proof. The proposed amendments would require that a party filing objections simultaneously file a written offer of proof supporting the objections as described above in relation to § 102.66(b). The proposed change is based on the view that objections to a secret-ballot election should not be filed by any party lacking factual support for the objections and, therefore, that a filing party should be able to describe the facts supporting its objections at the time of filing. The proposed amendments codify existing practice permitting parties to file, but not serve, evidence in support of objections.

The proposed amendments would also codify existing practice permitting the regional director to investigate the objections by examining evidence offered in support thereof to determine if a hearing is warranted. Thus, if there are potentially determinative challenges or the regional director determines that objections together with an accompanying offer of proof raise a genuine issue of material fact, the proposed amendments would require that the regional director serve a notice

[55] A comparison of the total number of elections to the total number of grants of review (including grants of review after petitions were dismissed) during the period 2002 to 2009 reveals that review was granted in less than 1.3 percent of all representation cases in which an election was conducted and in approximately 15 percent of those cases in which a request was filed. See NLRB Annual Reports (Fiscal Years 2001–2009) and NLRB Office of the General Counsel, Summaries of Operations (Fiscal Years 2002–2009 with 2002 including summary for 2001).

of hearing setting the matters for hearing within 14 days of the tally or as soon thereafter as practicable. If the resolution of questions concerning the eligibility of individuals in the unit was deferred by the hearing officer, as described in § 102.66 above, and the votes of such individuals are potentially outcome determinative, the deferred questions would be addressed in the post-election hearing. The proposed amendments would further provide that any such hearing would open with the parties stating their positions on any challenges and objections, followed by offers of proof as described above in relation to § 102.66.

The proposed amendments would provide that if no potentially determinative challenges exist and no objections are filed, any party may file a request for review of the regional director's decision and direction of election within 14 days of the tally. If there are potentially determinative challenges or objections, a request for review of the regional director's decision and direction of election may be filed within 14 days of the regional director's disposition of the post-election disputes and may be consolidated with any request for review of post-election rulings.

The proposed amendments would create a uniform procedure in those cases in which there are potentially outcome determinative challenges or the regional director determines that objections together with an accompanying offer of proof raise genuine issues of material fact that must be resolved. Adopting the procedure currently contained in §§ 102.69(d) and (e), the proposed amendments would provide that, in such cases, the regional director shall provide for a hearing before a hearing officer who shall, after such hearing, issue a report containing recommendations as to the disposition of the issues. Within 14 days after issuance of such a report, any party may file exceptions with the regional director. Finally, consistent with the proposed changes described above in relation to § 102.62, the proposed amendments would make Board review of a regional director's resolution of post-election disputes discretionary in cases involving directed elections as well as those involving stipulated elections.[56] The Board anticipates that this proposed change would leave a higher percentage of final decisions concerning disputes arising out of representation proceedings with the Board's regional directors who are members of the career civil service.

Subparts D and E, §§ 102.73 Through 102.88, Procedures for Unfair Labor Practice and Representation Cases Under Section 8(b)(7) and 9(c) of the Act and Procedures for Referendum Under Section 9(e) of the Act

The proposed amendments in these two subparts are intended solely to conform their provisions to the amendments in Subpart C described above.

Subpart I—Service and Filing of Papers

Sec. 102.112 Date of Service; Date of Filing

The proposed amendments would correct an omission concerning the effective date of service by electronic mail.

Sec. 102.113 Methods of Service of Process and Papers by the Agency; Proof of Service

The proposed amendments would add electronic mail as an approved method of service of Board papers other than complaints, compliance specifications, final decisions and orders in unfair labor practice cases, and subpoenas. The existing rules include regular mail, private delivery service and facsimile transmission (with consent), along with personal service and certified and registered mail. Section 102.114 has provided for service of parties' papers by electronic mail since 2009.

Sec. 102.114 Filing and Service of Papers; Form of Papers; Manner and Proof of Filing and Service; Electronic Filings

The proposed amendments to this section are intended solely to conform its provisions to the amendments in Subpart C described above.

Part 103, Subpart B—Election Procedures

Sec. 103.20 Posting of Election Notices

The proposed amendments eliminate this section, the only section of part 103 of the regulations governing procedures in representation proceedings, and integrate its contents into part 102, modified as explained above in relation to § 102.67.

Request for Comment Regarding Blocking Charges

Just as the Board seeks through the proposed amendments to prevent any party from using the hearing process established under section 9 of the Act to delay the conduct of an election though unnecessary litigation, the Board also believes that no party should use the unfair labor practice procedures established under sections 8 and 10 to unnecessarily delay the conduct of an election. As set forth in the Casehandling Manual, ''The Agency has a general policy of holding in abeyance the processing of a petition where a concurrent unfair labor practice charge is filed by a party to the petition and the charge alleges conduct that, if proven, would interfere with employee free choice in an election, were one to be conducted.'' Section 11730. This ''blocking charge'' policy is not set forth or implemented in the current rules, but it has been applied by the Board in the course of adjudication.[57]

The Board therefore specifically invites comment on whether any final amendments should include changes in the current blocking charge policy as described in sections 11730 to 11734 of the Casehandling Manual or whether any changes in that policy should be made by the Board through means other than amendment of the rules. The Board further specifically invites interested parties to comment on whether the Board should provide that (1) any party to a representation proceeding that files an unfair labor practice charge together with a request that it block the processing of the petition shall simultaneously file an offer of proof of the type described in relation to §§ 102.66(b) and 102.69(a); (2) if the regional director finds that the party's offer of proof does not describe evidence that, if introduced at a hearing, would require that the processing of the petition be held in abeyance, the regional director shall continue to process the petition; (3) the party seeking to block the processing of a

[56] The Board anticipates that permitting it to deny review of regional directors' resolution of post-election disputes—when a party's request raises no compelling grounds for granting such review—would eliminate the most significant source of administrative delay in the finality of election results. Together with simultaneous filing of objections and offers of proof and prompt scheduling of post-election hearings, when they are necessary, the Board anticipates that the proposed amendments would reduce the period of time between the tally of votes and certification of the results. Such an outcome would reduce the time during which employers are uncertain about their legal obligations because, after a tally showing a majority vote in favor of representation, employers violate the duty to bargain by unilaterally changing the status quo only if a representative is ultimately certified. See *Mike O'Conner Chevrolet,* 209 NLRB 701, 703 (1974).

[57] See, *e.g., Bally's Atlantic City,* 338 NLRB 443 (2002). See generally Berton B. Subrin, *The NLRB's Blocking Charge Policy: Wisdom or Folly?,* 39 LAB. L.J. 651 (1988).

petition shall immediately make the witnesses identified in its offer of proof available to the regional director so that the regional director can promptly investigate the charge as required by section 11740.2(c) of the Casehandling Manual; (4) unless the regional director finds that there is probable cause to believe that an unfair labor practice was committed that requires that the processing of the petition be held in abeyance, the regional director shall continue to process the petition; (5) if the Regional Director is unable to make such a determination prior to the date of the election, the election shall be conducted and the ballots impounded; (6) if the regional director finds that there is probable cause to believe that an unfair labor practice was committed that would require that the processing of the petition be held in abeyance under current policy, the regional director shall instead conduct the election and impound the ballots; (7) if the regional director finds that there is probable cause to believe that an unfair labor practice was committed that would require that the petition be dismissed under section 11730.3 of the Casehandling Manual, the regional director shall instead conduct the election and impound the ballots; (8) the blocking charge policy is eliminated, but the parties may continue to object to conduct that was previously grounds for holding the processing of a petition in abeyance and the objections may be grounds for both overturning the elections results and dismissing the petition when appropriate; or (9) the blocking charge policy should be altered in any other respect.

IV. Response to Dissent

The dissent, which is printed below, criticizes both the procedure followed by the Board in proposing and seeking public comment on the possible reforms set forth in this Notice and the content of the proposed amendments. Many of these criticisms are based on inaccurate characterizations of this rulemaking proceeding, the substance of the proposed amendments, and the historical context in which they arise. However, to the extent that the dissent reflects the legitimate concerns of participants in the Board's representation case procedures and of other members of the public affected by those procedures, it offers precisely the kind of commentary that the Board hopes and expects to receive during the comment period and will consider carefully before issuing any final rule.

The dissent acknowledges that this rulemaking is being conducted in full compliance with all of the numerous and substantial legal requirements governing such proceedings. Yet it declares such compliance with congressional commands ''utterly beside the point,'' seeking to portray this proceeding as an attempt to deny interested members of the public the opportunity to communicate to the Board their views on the subjects addressed by the proposed amendments. In fact, this proceeding has been designed to elicit the broadest and most detailed public input on the subject of representation case procedure in the 76-year history of the agency.

The Board's procedures relating to the conduct of elections were first established in 1935. They have since been changed administratively on at least three dozen occasions. The Board has only rarely utilized the Administrative Procedure Act's notice-and-comment rulemaking procedure; most often the Board simply implemented the changes without prior notice or request for public comment. This procedure was permissible because notice and comment is not required in order to promulgate or amend ''rules of agency organization, procedure, or practice.'' See 5 U.S.C. 553(b)(A). The vast majority of the amendments proposed herein are procedural in nature, and the Board was not required to proceed by notice and comment with respect to them. The Board has nevertheless, in the interest of maximizing public participation, chosen to give notice and seek public comment as to all of the proposed amendments.[58]

The dissent criticizes the Board's publication of the text of proposed amendments prior to soliciting public comments on their subject matter, characterizing it as a limitation on public participation in the rulemaking process. In fact, the publication of proposed rules greatly enhances the opportunity for interested members of the public to submit meaningful comments. This level of disclosure is not required by the Administrative Procedure Act; it would suffice legally for the Board simply to describe the substance of the proposed amendments. However, the Board has chosen to maximize the openness of the process by disclosing in as much detail as possible its thinking at this preliminary stage of the rulemaking process. It is expected that providing proposed rule text in addition to more general descriptions and explanations will enable interested members of the public to understand the proposals in greater depth and to submit more specific and useful comments. It is because of the value that the Board places on public comment that it has elected to provide notice of the proposed rulemaking in the most detailed form possible.

The dissent's use of the Board's health-care unit rulemaking proceeding as a benchmark is inapt. Even that proceeding generated fundamental disagreement among the Board members about the purpose and possible value of rulemaking.[59] For all of its length and complexity, that proceeding led not to consensus among stakeholders, or even to grudging acceptance of the Board's rule, but to litigation that culminated only with a Supreme Court decision upholding the Board's action. *American Hospital Ass'n* v. *NLRB,* 499 U.S. 606 (1991). Nor is it clear that the procedure followed by the Board—described by one commentator as ''procedural overkill''—actually generated more useful information, in a cost-effective way, than a simpler, shorter proceeding would have provided.[60] In any case, the

[58] The Board's approach here is consistent with its recent solicitations of briefs from the broader labor-management community in connection with pending cases. See, *e.g., Specialty Healthcare,* 356 NLRB No. 56 (2010). There, the Board majority stated its strong belief ''that asking all interested parties to provide [the Board] with information and argument * * * is the fairest and soundest method of deciding whether our rules should remain the same or be changed and, if the latter, what the new rules should be.'' Slip op. at 2. In dissent, Member Hayes disagreed, arguing that ''copious information is already available in-house'' and predicting that ''what [the Board] will receive will be mostly subjective or partisan justification for changing the law rather than any useful information.'' *Id.* at 5. See also *Rite-Aid Store 6473–Lamons Gasket Co.,* 355 NLRB No. 157, slip op. at 5 (dissent of Members Schaumber and Hayes) (observing that in response to invitation to file briefs, ''Board will predictably receive mostly subjective and partisan claims'' critical of current precedent and that ''Board already has its own reliable and objective empirical data for evaluation'').

[59] See Mark H. Grunewald, *The NLRB's First Rulemaking: An Exercise in Pragmatism,* 41 Duke L.J. 274, 290 (1991). (''The disagreement over the usefulness of rulemaking became even more contentious when the discussion turned to the question of whether to include a specific proposal in the notice of proposed rulemaking or merely to indicate an intent to make a rule on the subject of health care units.'').

[60] As one scholar observed, in a study prepared for the Administrative Conference of the United States:

Almost two years elapsed between the time when the Board decided to engage in rulemaking and when it issued the final rule. During this period, substantial staff time, including a significant amount of high-level staff time, was used to manage the rulemaking and to assist in the analysis of the product of the hearings and comment periods. * * * Not only was the time commitment significant as an absolute matter, but also because regular staff rather than special rulemaking staff was used, this staff time was thus invested at a cost to other matters. * * * Moreover, a portion of the two years was consumed with a procedure not required for notice and comment rulemaking—multi-location hearings with an opportunity for a form of cross-examination. * * * Under the circumstances of this rulemaking, particularly its

contrast between the subject matter of the health care rulemaking—the nature and organization of work in a complex industry on a nationwide basis—and the current proceeding could not be greater. No party possesses greater knowledge of the Board's own procedures than the Board itself.[61] Parties to representation cases would of course be affected by changes in the Board's procedures, including in ways that may not be obvious to the Board; their detailed written commentary is therefore being solicited and will be carefully considered before any changes are effectuated. In addition, the Board intends to issue a notice of public hearing to be held in Washington, DC, on July 18–19, at which it will hear public comments on the proposed amendments as well as such other ideas as speakers may wish to offer for improvement of the representation case process. But the suggestion that a proceeding similar to the one conducted for purposes of health-care unit rulemaking is needed here fails to consider the differences in the subject matters in the respective proceedings.

This misapprehension also leads the dissent to criticize the opportunities for public comment provided here as too brief. Our colleague concedes that the initial 60-day period violates no statutory or other requirement that applies to the rulemaking process. Indeed, a 60-day period has become a common benchmark. See, *e.g.,* E.O. No. 13563 (''Improving Regulation and Regulatory Review''), 76 FR 3821 (Jan. 18, 2011); E.O. No. 12866 (''Regulatory Planning and Review''), 58 FR 51735 (Sept. 30, 1993). Measured against the comment periods adopted by other agencies, the period provided for here is hardly abnormally short. *See* Steven J. Balla, *Brief Report on Economically Significant Rules and the Duration of Comment Periods, http://www.acus.gov/wp-content/uploads/downloads/2011/04/COR-Balla-Supplemental-Research-Brief.pdf* (2011) (the average duration of the comment periods for proposed actions that are economically significant is 45.1 days, and 38.7 days for all other types of actions). Moreover, the 60-day initial comment period will be followed by a 14-day reply period and will be supplemented with a public hearing.

As to the substance of the proposed amendments, the dissent raises a number of important questions of policy. These questions will be considered carefully in arriving at a final rule. However, the dissent also contains several errors that are worth pointing out:

The dissent states that the proposed amendments will ''substantially limit the opportunity for full evidentiary hearing or Board review on contested issues.'' In fact, the proposed amendments simply import the norms of modern civil procedure from the federal judicial system and apply them to adjudication of representation-case issues. The proposed amendments would require the parties to identify the issues that separate them and the evidence supporting their respective positions and permit an evidentiary hearing only as to triable issues of material fact. Like the Federal Rules of Civil Procedure, the proposed amendments would do away with litigation for the sake of litigation, allowing only litigation that is genuinely needed to resolve disputed issues material to the outcome of the case. The Board expects that this reform alone would result in substantial savings to both the parties and the agency, given the high cost of litigation. As to Board review, there is no issue as to which any party's right to seek Board review is proposed to be eliminated. Rather, in the interest of efficiency, requests for Board review would be consolidated into a single post-dismissal or post-election request instead of the pre-election request and post-election exceptions permitted under current practice, and review of regional director's resolution of post-election disputes would be discretionary as is currently the case in relation to pre-election disputes. Again, it is expected that the proposed reform would result in substantial savings to the parties and the public.

The dissent also contends that the proposed amendments will ''substantially shorten the time between the filing of the petition and the election date,'' and that the purpose of this change is ''to effectively eviscerate an employer's legitimate opportunity to express its views about collective bargaining'' in order to increase the election success rate of unions. That accusation is unwarranted. The Board seeks to gain the efficiency and savings that would result from streamlining of its procedures. What effect the proposed changes would have on the outcome of elections is both unpredictable and immaterial. The dissent's charges ignore important facts about the proposed amendments: (1) The proposed rules would apply equally to all parties and to both elections seeking to certify and to decertify a representative of employees; (2) the limitations on evidentiary hearings would apply equally to pre- and post-election hearings; (3) the proposed rules would likely shorten post-election proceedings by avoiding altogether litigation of issues that are mooted by election results, among other efficiencies, eliminating unnecessary litigation, and by substituting a request for review procedure for the current exceptions procedure; and (4) the proposed rules do not impose any limitations on the election-related speech of any party.

Finally, the dissent relies heavily on the fact that the agency has met its own time targets for the processing of representation cases. But those time targets have been set in light of the agency's current procedures, including their built-in inefficiencies. The history of congressional and administrative efforts in the representation-case area has consisted of a progression of reforms to reduce the amount of time required to ultimately resolve questions concerning representation, which, as Congress has found, can disrupt the workplace and interfere with interstate commerce. With each reform, the waiting time has been reduced, the result has been widely viewed as progress, and the achievement of the full measure of time savings by agency employees has been lauded as success. The Board conceives of the proposed amendments as the next step for the agency in improving its performance of this critical part of its statutory mission.

V. Dissenting View of Member Brian E. Hayes

Member Hayes, dissenting,

Today, my colleagues undertake an expedited rulemaking process in order to implement an expedited representation election process. Neither process is appropriate or necessary. Both processes, however, share a common purpose: To stifle full debate on matters that demand it, in furtherance of a belief that employers should have little or no involvement in the resolution of questions concerning representation. For my part at least, I can and do dissent.

First, the rulemaking process:

The last substantive rulemaking effort of comparable scale involved the determination of appropriate bargaining

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novelty for the Board, the hearings were probably a desirable choice. Certainly as a legal matter, however, and perhaps as a practical matter, the hearings were procedural overkill and the burdens created by the number and structure of the hearings would have to be considered as part of the overall cost-benefit evaluation of the rulemaking.

Grunewald, *NLRB's First Rulemaking,* supra, 41 Duke L.J. at 319–320.

[61] The Supreme Court has made clear that, ''[a]bsent constitutional constraints or extremely compelling circumstances,'' it is a ''very basic tenet of administrative law that agencies should be free to fashion their own rules of procedure,'' consistent with statutory requirements. *Vermont Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council,* 435 U.S. 519, 543–44 (1978).

units in the health care industry. The need for this effort was obvious, based on years of litigation highlighting specific problems and differences among the Board, the courts of appeals, and health care industry constituents. The initial July 2, 1987 notice of proposed rulemaking was followed by a series of four public hearings, the last one held over a 7-day period, in October 1987. Thereafter, the written comment period was extended. Another rulemaking notice followed on September 1, 1988. It reviewed the massive amount of oral testimony (3545 pages and 144 witnesses) and written comments (1500 pages filed by 315 individuals and organizations) received during the prior year and announced a revised rule with another 6-week period for written comment. The final rule was published on April 21, 1989, almost 2 years after the initial notice.

In marked contrast to the health care unit rulemaking, my colleagues put forth proposals on their own initiative, not in response to any petition for rulemaking or in response to any specific problems defined by prior litigation. The need for their proposed electoral reform, which directly affects every employer and employee in every industry subject to Board jurisdiction, is far from obvious. The proposed revisions largely reflect the narrow concerns and proposals of a few academicians.[62] Rather than proceeding with the preparation and publication of rules responsive to just this one small and ideologically homogenous group, it was incumbent on the Board to have a far more inclusive public discussion of the need for electoral reform *before* determining what rule revisions to propose formally in the **Federal Register**.[63] In this regard, President Obama's Executive Order 13563 specifically states that ''*[b]efore* issuing a notice of proposed rulemaking, each agency, where feasible and appropriate, shall seek the views of those who are likely to be affected, including those who are likely to benefit from and those who are potentially subject to such rulemaking.''[64] While this Order is not binding on the Board, as an independent agency, ''such agencies are encouraged to give consideration to all of its provisions, consistent with their legal authority.''[65]

It was both ''feasible and appropriate'' for the Board to seek the views of those likely to be affected before issuing the notice of proposed rulemaking. At the very least, the proposals should have been previewed for comment by the Board's standing Rules Revision Committee, a group of agency officials specifically identified as responsible for considering and recommending modifications in existing rules and proposed new rules,[66] and by the Practice and Procedures Committee of the American Bar Association, a group representative of the broad spectrum of private and public sector labor-management professionals that frequently serves as a sounding board for revisions of our Rules. I believe the Board should also have exercised its discretion to hold an open meeting under the Government in Sunshine Act[67] when voting to authorize a rule revision proposal.[68] Alternatively, the Board could have undertaken negotiated rulemaking.[69] Any of the suggested processes could have encouraged consensus in rulemaking, rather than the inevitably divisive approach my colleagues have chosen by publishing their proposed rules with no advance notice or public discussion of their purpose or content.

The limitation on public participation in this process continues with my colleagues' choice of a 60-day written comment period, a 14-day reply period, and one public hearing for discussion about the proposed rules. Again, the contrast with health care unit rulemaking is marked. While I do not suggest that the proposed rulemaking process needs to last 2 years, I think it manifest that 2 and a half months in the dead of summer is too little time, and written comment with a single hearing is too limited a method, for public participation in discussing the myriad issues raised. There needs to be a more extended comment period and a full opportunity for broad stakeholder input through multiple public hearings on proposed rules of this magnitude.

It is utterly beside the point, and should be of little comfort to the majority, that its actions may be in technical compliance with the requirements of the Administrative Procedure Act (APA) and other regulations bearing on the rulemaking process. President Obama's Memorandum on Transparency and Open Government, issued on January 21, 2009,[70] makes clear that independent agencies have an obligation to do much more than provide minimum due process in order to assure that our regulatory actions implement the principles of transparency, participation, and collaboration. As explained in the subsequent directive from the Director of the Office of Management and Budget, these principles ''form the cornerstone of an open government.''[71] Sadly, my colleagues reduce that cornerstone to rubble by proceeding with a rulemaking process that is opaque, exclusionary, and adversarial.[72] The sense of fait accompli is inescapable.

Now, to the proposed rules themselves:

Parts of what my colleagues propose seem reasonable enough. On the other hand, the whole of proposed reform is much, much more than the sum of its parts and out of all proportion to specific problems with the Board's current representation casehandling procedures. While the preamble frequently refers to the Board's interest in the expeditious resolution of questions concerning representation,

[62] *E.g.,* Charles Craver, *The National Labor Relations Act at 75: In Need of a Heart Transplant,* 27 Hofstra Lab. & Emp. L.J. 311 (2010); William B. Gould, *The Employee Free Choice Act of 2009, Labor Law Reform, and What Can Be Done About the Broken System of Labor-Management Relations Law in the United States,* 43 U.S.F.L. Rev. 291 (2008); Charles J. Morris, *Renaissance at the NLRB—Opportunity and Prospect for Non-Legislative Procedural Reform at the Labor Board,* 23 Stetson L. Rev. 101 (1993).

[63] I disagree with my colleagues' characterization of the proposed rule revisions as ''almost entirely'' procedural in nature. Accordingly, I find that the notice and comment procedure is mandatory, not discretionary.

[64] E.O. 13563, 76 FR 3821, 3821–23 (Jan. 21, 2011) (emphasis added).

[65] Office of Management and Budget Memo 11–10, Memorandum for the Heads of Executive Departments and Agencies, and of Independent Regulatory Agencies: Executive Order 13563, ''Improving Regulation and Regulatory Review'' (February 2, 2011), available at *http://www.whitehouse.gov/omb/memoranda.*

[66] See May 23, 2011, letter from Board Executive Secretary submitting the Board's Preliminary Plan to Review Significant Regulations to the OMB Office of Information and Regulatory Affairs in response to Section 6 of Executive Order 13563, available at *http://www.slideshare.net/whitehouse/national-labor-relations-board-preliminary-reform-board.*

[67] Government in the Sunshine Act, 5 U.S.C. 552b.

[68] My point is not that the process followed to date is impermissible. It is that a more open public process would be far more preferable and consistent with Executive Order guidelines.

[69] See Negotiated Rulemaking Act, 5 U.S.C. 561 *et seq.*

[70] 74 FR 4685, 4685–86 (Jan. 26, 2009).

[71] Office of Management and Budget Memo 10–06, Memorandum for the Heads of Executive Departments and Agencies: Open Government Directive (February 2, 2011), available at *http://www.whitehouse.gov/omb/memoranda.*

[72] The majority suggests an inconsistency between my dissenting position in *Specialty Healthcare and Rehabilitation Center of Mobile,* 356 NLRB No. 56 (2010), and in the present rulemaking scenario. In both instances, I find that the majority has provided an insufficient explanation for reexamining extant law and procedure. In *Specialty,* an adjudicatory proceeding, I further objected to the expansion of inquiry far beyond the issues specifically raised by the parties. That inquiry, if undertaken, should have entailed the rulemaking process.

there is no certainty that the rule revisions even address the problems that have caused undue delay in a very small number of representation cases or that they will shorten the *overall* timeframe for processing an election case from the filing of a petition until final resolution. What *is* certain is that the proposed rules will (1) substantially shorten the time between the filing of the petition and the election date, and (2) substantially limit the opportunity for full evidentiary hearing or Board review on contested issues involving, among other things, appropriate unit, voter eligibility, and election misconduct. Thus, by administrative fiat in lieu of Congressional action, the Board will impose organized labor's much sought-after ''quickie election'' option, a procedure under which elections will be held in 10 to 21 days from the filing of the petition. Make no mistake, the principal purpose for this radical manipulation of our election process is to minimize, or rather, to effectively eviscerate an employer's legitimate opportunity to express its views about collective bargaining.

It may be best to begin a substantive analysis of the proposed rules with an accounting of the Board's current representation casehandling procedures. The Acting General Counsel's summary of operations for Fiscal Year 2010 took special note of facts that: (1) 95.1 percent of all initial elections were conducted within 56 days of the filing of the petition; (2) initial elections were conducted in a median of 38 days from the filing of the petition; and (3) the agency closed 86.3 percent of all representation cases within 100 days, surpassing an internal target rate of 85 percent.[73] The Acting General Counsel described the achievement of these results as ''outstanding.''[74]

The Board's total representation case intake for Fiscal Year 2010 (including all categories of election petitions) was 3,204, a 10 percent increase from the Fiscal Year 2009 intake of 2,912. For all petitions filed, the average time to an election was 31 days. Voluntary election agreements were obtained in 92 percent of the merit petitions. In contested cases, Regional Directors issued 185 pre-election decisions after hearing in a median of 37 days, well below the target median of 45 days. In 56 cases, post-election objections and/or challenges were filed that required an investigative hearing. Decisions or Supplemental Reports issued in those cases after hearing in 70 median days from the election or the filing of objections. In 32 cases, post-election objections and/or challenges could be resolved without a hearing. Decisions or Supplemental Reports in those cases issued in 22 median days. The General Counsel's goal in hearing cases is 80 median days and 32 days in non-hearing cases.[75]

It is not at all apparent from the foregoing statistical picture why my colleagues have decided that it is now necessary to (1) eliminate pre-election evidentiary hearings, as much as is statutorily permissible (or arguably well beyond that point), (2) eliminate pre-election requests for review and defer decision on virtually all issues heretofore decided at the preelection stage in the small percentage of contested cases, (3) impose pleading requirements and minimal response times on election parties, most notably on employers, who risk forfeiture of the right to contest issues if they fail timely to comply with these requirements, and (4) eliminate any automatic right to post-election Board review of contested issues.

I absolutely agree that the Board should be concerned about unreasonable delay in any case, particularly in those involving questions concerning representation. It should never take 424 days from the filing of a petition to resolve pre-election issues, as happened with respect to one case in Fiscal Year 2010;[76] nor should it take years to resolve post-election objections, as it did in a trio of recently-decided Board cases.[77] However, as measured by the Board and General Counsel's own time targets and performance goals, such delay is the exception rather than the norm. Notably, my colleagues make no reference to these time targets while drastically departing from them when reducing the number of days from petition filing to an election. Further, the majority makes no effort whatsoever to identify the specific causes of delay in those cases that were unreasonably delayed. Without knowing which cases they were, I cannot myself state with certainty what caused delay in each instance, but I can say based on experience during my tenure as Board member that vacancies or partisan shifts in Board membership and the inability of the Board itself to deal promptly with complex legal and factual issues have delayed final resolution far more often than any systemic procedural problems or obstructionist legal tactics. That was the situation in each of the aforementioned extremely delayed cases, and in none of those cases would the majority's current proposals have yielded a different result.

Further, it is far from clear that shortening the time period from the filing of a petition to the conduct of an election will have the corresponding effect of shortening the median time from filing to final resolution, which should be the primary goal of any revision of the rules. Again, the majority provides no explanation. By impeding the process of timely resolving pre-election issues and eliminating any right to automatic Board review of regional decisions, the proposed revisions seemingly discourage parties from entering into any form of election agreement, thereby threatening the current high percentage of voluntary election agreements. In addition, at least in those cases where the union wins the election, the deferral of pre-election issues seems merely to add time from the pre-election period to the post-election period, with no net reduction in overall processing time. This will not save time or money for the parties or the Board. Finally, the proposed rule revision permitting up to 20 percent of individuals whose eligibility is contested to cast challenged ballots casts a cloud of uncertainty over the election process. Employees who do belong in the bargaining unit may be so mislead about the unit's scope or character that they cannot make an informed choice, instead basing their vote on perceived common interests or differences with employee groups that ultimately do not belong in the unit.[78]

The oft-repeated aim of the Board to resolve questions concerning representation expeditiously does not mean that we must conduct elections in as short a time as possible In truth, the

[73] General Counsel Memorandum 11–03 at ''Introduction'' (Jan. 10, 2011), available at *http://www.nlrb.gov/publications/general-counsel-memos.* Agency performance has continued at essentially the same level for the first 3 months of fiscal year 2011. See GC Memo 11–09, supra at 18.

[74] GC Memo11–03, supra at ''Introduction.''

[75] GC Memo11–09, supra at 18.

[76] *Kansas City Repertory Theatre,* 17–CA–12647.

[77] *Jury's Boston Hotel,* 356 NLRB No. 114 (2011), *Mastec/Direct TV,* 356 NLRB No. 110 (2011), and *Independence Residences, Inc.,* 355 NLRB No. 153 (2010).

[78] As stated by the Fourth Circuit in *NLRB* v. *Beverly Health and Rehabilitation Services, Inc.,* No. 96–2195, 1997 WL 457524, at *4 (4th Cir. 1997):

> Where employees are led to believe that they are voting on a particular bargaining unit and that bargaining unit is subsequently modified post-election, such that the bargaining unit, as modified, is fundamentally different in scope or character from the proposed bargaining unit, the employees have effectively been denied the right to make an informed choice in the representation election. *See NLRB* v. *Parsons Sch. of Design,* 793 F.2d 503, 506–08 (2d Cir.1986); *Lorimar Productions,* 771 F.2d at 1301–02; *Hamilton Test Sys.,* 743 F.2d at 140–42. Thus, the Board may not ''inform employees that they are voting for representation in [one] unit and later * * * consider the ballot as a vote for representation in a [different] unit.'' *Hamilton Test Sys.,* 743 F.2d at 140; *see also Lorimar Productions,* 771 F.2d at 1301 (quoting *Hamilton Test Sys.*).

''problem'' which my colleagues seek to address through these rule revisions is not that the representation election process generally takes too long. It is that unions are not winning more elections. The perception that this is a problem is based on the premise, really more of an absolute article of faith, that employer unfair labor practices greatly distort the representation election process. This leads to the conclusion that the more limited a role an employer has in this process, the less opportunity it will have to coerce employees, and the greater the prospect that the election results will reflect employees' ''true'' choice on collective-bargaining representation, which will presumably mean a much higher percentage of union election victories. Inasmuch as unions prevailed in 67.6 percent of elections held in calendar year 2010 and in 68.7 percent of elections held in calendar year 2009,[79] the percentage of union victories contemplated by the majority in the revised rules must be remarkably high.

One way to limit employer participation is to shorten the time from petition filing to election date. Of course, limiting the election period does not operate selectively to deter unlawful coercive employer speech or conduct.[80] It broadly limits all employer speech and thereby impermissibly trenches upon protections that Congress specifically affirmed for the debate of labor issues when it enacted Section 8(c) in 1947. As the Supreme Court stated in *Chamber of Commerce* v. *Brown,* 554 U.S. 60, 67–68 (2008):

> From one vantage, § 8(c) ''merely implements the First Amendment,'' *NLRB* v. *Gissel Packing Co.,* 395 U.S. 575, 617, 89 S.Ct. 1918, 23 L.Ed.2d 547 (1969), in that it responded to particular constitutional rulings of the NLRB. See S.Rep. No. 80–105, pt. 2, pp. 23–24 (1947). But its enactment also manifested a ''congressional intent to encourage free debate on issues dividing labor and management.'' *Linn* v. *Plant Guard Workers,* 383 U.S. 53, 62, 86 S.Ct. 657, 15 L.Ed.2d 582 (1966). It is indicative of how important Congress deemed such ''free debate'' that Congress amended the NLRA rather than leaving to the courts the task of correcting the NLRB's decisions on a case-by-case basis. We have characterized this policy judgment, which suffuses the NLRA as a whole, as ''favoring uninhibited, robust, and wide-open debate in labor disputes,'' stressing that ''freewheeling use of the written and spoken word * * * has been expressly fostered by Congress and approved by the NLRB.'' *Letter Carriers* v. *Austin,* 418 U.S. 264, 272–73, 94 S.Ct. 2770, 41 L.Ed.2d 745 (1974).

Admittedly, the Court recognized the Board's right to police ''a narrow zone of speech to ensure free and fair elections,''[81] but neither the Court's reasoning nor the congressional intent to encourage free debate can be squared with my colleagues' proposal generally to limit the opportunity for employers to engage in a legitimate pre-election campaign opposing unionization.

Another way to limit employer participation is to reduce opportunities for litigation of contested issues before the Board. That is the transparent purpose of the proposed rules' transformation of discretionary questionnaires into mandatory pleading requirements and the imposition of limitations on full evidentiary hearings, briefing, and Board review. All of these revisions are focused on preventing parties, primarily employers, from litigating issues in representation proceedings, even when legitimate issues are raised and a full record and Board review would seem to be essential.

It is difficult to identify which proposed rule change is most egregious, but a solid candidate for that dishonor might be the expanded, mandatory ''questionnaire'' process. As described by the majority,[82] the proposed Statement of Position Form would require an employer to state its position on:

> the appropriateness of the petitioned-for unit; any proposed exclusions from the petitioned-for unit; the existence of any bar to the election; the type, dates, times, and location of the election; and any other issues that a party intends to raise at hearing. In those cases in which a party takes the position that the proposed unit is not an appropriate unit, the party would also be required to state the basis of the contention and identify the most similar unit it concedes is appropriate. In those cases in which a party intends to contest at the pre-election hearing the eligibility of individuals occupying classifications in the proposed unit, the party would be required to both identify the individuals (by name and classification) and state the basis of the proposed exclusion, for example, because the identified individuals are supervisors.

Such matters deserve inquiry and definition, hopefully leading to resolution, in the preelection process. However, the proposed rules further mandate that a hearing be held 7 days from service of the petition and the Statement of Position Form, and they bar a party from offering evidence or cross-examining witnesses as to any issue it did not raise in its own statement or in response to the statement of another party. In effect, a party must raise issues and state its basis for raising them in a maximum of 7 days or forfeit all legal right to pursue those issues. It may be that employers of a certain size have legal counsel or labor consultants readily available to evaluate the election petition and proposed bargaining unit, identify any issues to be contested, and prepare the required statement in a week or less. However, the Board conducts many representation elections among employees of small business owners who have no such counsel readily at hand, have no idea how to obtain such counsel in short order, and are themselves unaware of such legal arcania as appropriate unit, contract bar, statutory supervisory status, and voter eligibility. The proposed rules, if implemented, will unconscionably and impermissibly deprive these small business owners of legal representation and due process.[83]

There is yet another aspect of the proposed rules' impact on employers that deserves mention. Under current law, an employer's obligation to bargain with a union attaches from the election date. Thus, an employer acts at its peril when making any unilateral changes pending resolution of post-election issues if the Board ultimately certifies the union's representative status.[84] Those post-election issues have heretofore been limited to election objections and challenges. Now, with the shift of virtually all pre-election issues to the post-election phase, the majority substantially increases the potential costs to all employers who have the temerity to attempt to conduct normal business operations while contesting legitimate election issues. Of course, there is no comparable burden on unions.

The proposed rule revisions are cause enough for dissent. However, one cannot help but wonder if they are a prelude to further changes. The same academicians whose treatises have inspired the current proposal have also advocated a host of other initiatives

[79] ''Number of NLRB Elections Held in 2010 Increased Substantially from Previous Year,'' Daily Lab. Rep. (BNA), No. 85, at B–1 (May 3, 2011).

[80] Indeed, the ''quickie'' election procedure may not deter such conduct at all. Employers who are wont to use impermissible means to oppose unionization will simply be encouraged to act at the first hint of organizational activity, prior to the filing of an election petition.

[81] *Chamber of Commerce* v. *Brown,* supra at 74.

[82] The form itself is not appended to the notice of proposed rulemaking, as one might logically expect it to be.

[83] The majority relies in part on conformity of the proposed rules with practices under the Federal Rules of Civil Procedure, which are, of course, not binding on administrative agency proceedings and which the Board has steadfastly refused for decades to follow with respect to prehearing discovery in unfair labor practice proceedings.

[84] See *Mike O'Conner Chevrolet,* 209 NLRB 701, 703 (1974).

designed to give unions greater access to employees and to limit further the opportunities for employers to communicate their views on collective bargaining representation. These initiatives include requiring an employer to provide access to employees on its premises and conducting elections off-site, by mail ballot, or by electronic vote. Finally, proceeding on a parallel adjudicatory course, my colleagues have signaled a willingness to entertain petitions for bargaining units that have heretofore not been found appropriate under Section 9(b) and 9(c)(5) of the Act.[85] The Board has not finally decided any of these issues, but the mere pendency of them should raise substantial concerns among those commenting on the proposed election rule revisions. There exists the possibility that the Board has only just begun an unprecedented campaign to supplant congressional action, subvert legal precedent, and return labor relations law to the supposed ''golden era'' of the Wagner Act's early years.[86]

In sum, the Board and General Counsel are consistently meeting their publicly-stated performance goals under the current representation election process, providing an expeditious *and fair* resolution to parties in the vast majority of cases, less than 10 percent of which involve contested preelection issues. Without any attempt to identify particular problems in cases where the process has failed, the majority has announced its intent to provide a more expeditious preelection process and a more limited postelection process that tilts heavily against employers' rights to engage in legitimate free speech and to petition the government for redress. Disclaiming any statutory obligation to provide any preliminary notice and opportunity to comment, the majority deigns to permit a limited written comment period and a single hearing when the myriad issues raised by the proposed rules cry out for far greater public participation in the rulemaking process both before and after formal publication of the proposed rule. The majority acts in apparent furtherance of the interests of a narrow constituency, and at the great expense of undermining public trust in the fairness of Board elections. I dissent from this undertaking, and I anticipate that many public voices will join in opposing it in spite of the limited opportunity to comment.

[85] See *Specialty Healthcare,* supra.

[86] See Charles J. Morris, The Blue Eagle at Work: Reclaiming Democratic Rights in the American Workplace (Cornell Univ. Press 2005).

VI. Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (''RFA''), 5 U.S.C. 601 *et seq.,* requires agencies promulgating proposed rules to prepare an initial regulatory flexibility analysis and to develop alternatives, wherever possible, when drafting regulations that will have a significant impact on a substantial number of small entities. The focus of the RFA is to ensure that agencies ''review rules to assess and take appropriate account of the potential impact on small businesses, small governmental jurisdictions, and small organizations, as provided by the [RFA].'' E.O. 13272, Sec. 1, 67 FR 53461 (''Proper Consideration of Small Entities in Agency Rulemaking''). An agency is not required to prepare an initial regulatory flexibility analysis for a proposed rule if the Agency head certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b).

As explained below, the Board concludes that the proposed amendments will not affect a substantial number of small entities. In any event, the Board further concludes that the proposed amendments will not have a significant economic impact on such small entities. Accordingly, the Agency Chairman has certified to the Chief Counsel for Advocacy of the Small Business Administration (''SBA'') that the proposed amendments will not have a significant economic impact on a substantial number of small entities.

The RFA does not define either ''significant economic impact'' or ''substantial'' as it relates to the number of regulated entities. 5 U.S.C. 601. In the absence of specific definitions, ''what is 'significant' or 'substantial' will vary depending on the problem that needs to be addressed, the rule's requirements, and the preliminary assessment of the rule's impact.'' See *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act,* Office of Advocacy, U.S. Small Business Administration at 17 (available at www.sba.gov) (''SBA Guide'').

The Board has determined that the proposed amendments would not affect a substantial number of small entities within the meaning of 5 U.S.C. 605(b). There are approximately six million private employers in the United States, the vast majority of which are classified as small entities under the Small Business Administration's standards.[87] Nearly all of those employers are subject to the Board's jurisdiction.[88] Because, under section 9 of the Act, parties have filed fewer than 4,000 petitions per year for the past five years and the Board has conducted fewer than 2,500 elections per year for the past five years,[89] the number of small employers participating in representation proceedings each year is less than one-tenth of one percent of the small employers in this country. Moreover, the employers that would be affected by the proposed amendments are not concentrated in one or a few sectors, but are found in every sector and industry subject to the Board's jurisdiction. Accordingly, the Board finds that the proposed amendments would not affect a substantial number of small entities within the meaning of 5 U.S.C. 601.

In any event, the Board estimates that the net effect of the proposed amendments could be to decrease costs for small entities. While certain of the proposed amendments—when viewed in isolation—could result in small cost increases, those costs should be more than offset by the many efficiencies in the Board's representation procedures created by the proposed amendments. For example, by permitting electronic filing, providing greater transparency and compliance assistance, reducing the length of evidentiary hearings, deferring litigation of issues that may be rendered moot by elections, deferring requests for review that may be rendered moot by elections, consolidating requests for review into a single proceeding, and making such review discretionary, the proposed amendments should help small entities conserve resources that they might otherwise expend when they are involved in a representation case under the Board's current rules and regulations.

To the extent that any individual requirements—isolated from the

[87] The Small Business Administration estimates that of the roughly six million private sector employers in 2007, all but about 18,300 were small businesses with fewer than 500 employees. *Source:* SBA Office of Advocacy estimates based on data from the U.S. Department of Commerce, Bureau of the Census, and trends from the U.S. Department of Labor, Bureau of Labor Statistics, Business Employment Dynamics.

[88] The principal private sector employers exempt from the Board's jurisdiction are employers of agricultural laborers and firms covered by the Railway Labor Act, 45 U.S.C. 151. See section 2 of the National Labor Relations Act, 29 U.S.C. 152(2), (3). Employers whose connection to interstate commerce is so slight that they do not satisfy the Board's discretionary jurisdictional standards are also treated as exempt. See 29 U.S.C. 164(c); An Outline of Law and Procedure in Representation Cases, Chapter 1, found on the Board's Web site, *http://www.nlrb.gov.*

[89] See NLRB Office of the General Counsel, Summaries of Operations (Fiscal Years 2006–2010) (reporting that the annual number of representation elections conducted decreased from 2,296 to 1,790).

proposed amendments' overall efficiencies—could impose additional costs on small entities, those added costs would be de minimus. Indeed, even when aggregated, the potential additional costs that a small entity could face in a given representation proceeding would still be minimal. For example, four new requirements in the proposed amendments might impose a cost on small employers: (1) Posting and electronic distribution of the Board's preliminary election notice and electronic distribution of the final notice; (2) completing the substantive portions of the Statement of Position form at or before any pre-election hearing; (3) providing the petitioner and the regional director with a list of the names and job information, and providing the regional director with contact information, for the employees at issue at or before any pre-election hearing; and (4) providing the petitioner and the regional director with additional job and contact information concerning employees eligible to vote following approval of an election agreement or issuance of a direction of election.

The proposed amendments' new notice requirements would involve merely posting paper copies of notices that will be sent to the employer by the regional director, as well as taking the few minutes to electronically distribute electronic versions of those notices, also supplied by the regional director, if the employer already regularly communicates with its employees over e-mail or via a Web site. The substantive portions of the Statement of Position form would only require a small employer to reduce to writing the positions on several issues that it would need to formulate, in any event, to effectively prepare for a pre-election hearing and which parties largely must already articulate at such a hearing under the current rules. And by entering into an election agreement, as do the vast majority of employers under the Board's current rules, a small employer would not have to complete the Statement of Position at all. The additional information to be supplied regarding voting employees should already be contained in employers' records, increasingly in readily retrievable electronic form, thereby allowing small employers to assemble such electronic lists without expending significant resources. Moreover, the typically small sizes of bargaining units at issue in Board elections (with medians ranging from 23 to 26 employees over the last decade) suggests that small employers will not be significantly burdened by having to provide the additional information.

For these reasons, the Board concludes that several of the proposed amendments would result in little to no adverse economic impact on the relatively few small entities who participate in representation proceedings each year, while the proposed amendments as a whole should actually reduce the costs incurred in connection with representation proceedings. Accordingly, the proposed amendments will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

These proposed amendments would not impose any information collection requirements. Accordingly, they are not subject to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*

The NLRB is an agency covered by the PRA. 44 U.S.C. 3502(1) and (5). The PRA establishes rules for such agencies' ''collection of information.'' 44 U.S.C. 3507.

The Board has considered whether any of the provisions of the proposed amendments provide for a ''collection of information'' covered by the PRA. Specifically, the Board has considered the following proposed provisions that contain petition and response requirements, posting requirements, and requirements that lists of employees or eligible voters be filed:

(1) Under the proposed amendments, as under the current rules, parties seeking to initiate the Board's representation procedures are required to file a petition with the Board containing specified information relevant to the Board's adjudication of the specific question raised by the filing of the petition. Under the proposed amendments, non-petitioning parties to such representation proceedings are required to file a Statement of Position setting forth the parties' positions and specified information relevant to the Board's adjudication of the question raised by the petition. Employers are currently asked to supply the portion of the information specified in the proposed amendments relating to their participation in interstate commerce.

(2) Under the proposed amendments, employers are required to post an initial and final notice to employees of an election. The second posting requirement exists currently. Employers are currently asked but not required to post the first notice (in a different form).

(3) Finally, under the proposed amendments, as under current case law, employers are required to file a list of eligible voters prior to an election. Under the proposed amendments, a preliminary list of employees is required at or before the pre-election hearing. For the reasons given below, the Board believes that none of these actions constitutes a collection of information covered by the PRA.

The PRA exempts from the definition of ''collection of information'' ''a collection of information described under section 3518(c)(1)'' of the Act. 44 U.S.C. 3502(3)(B).

Section 3518(c) provides:

- (c)(1) Except as provided in paragraph (2), this subchapter shall not apply to the collection of information—
  - (B) During the conduct of—
  - (ii) An administrative action or investigation involving an agency against specific individuals or entities;
- (2) This subchapter applies to the collection of information during the conduct of general investigations * * * undertaken with reference to a category of individuals or entities such as a class of licensees or an entire industry.

44 U.S.C. 3518(c). The legislative history of this provision makes clear that it is not limited to prosecutorial proceedings. The Senate Report on the PRA states, ''Section 3518(c)(1)(B) is not limited to agency proceedings of a prosecutorial nature but also include[s] any agency proceeding involving specific adversary parties.'' S. Rep. No. 96–930, at 56 (1980).

The Board believes that all of the above-described provisions of the proposed amendments fall within the exemption created by sections 3502(3)(B) and 3518(c)(1)(B)(ii). A representation proceeding under section 9 of the NLRA is ''an administrative action or investigation involving an agency.'' A representation proceeding is also ''against specific individuals or entities'' within the meaning of section 3518(c)(1)(B)(ii). The Board's decisions in representation proceedings are binding on and thereby alter the legal rights of the parties to the proceedings. For example, the employer of any employees who are the subject of a petition is a party to the resulting representation proceeding.[90] If the Board finds in a representation proceeding that a petition has been filed concerning an appropriate unit and that employees in that unit have voted to be represented, the Board will thereafter certify the petitioner as the employees' representative for purposes of collective bargaining with the employer. As a direct and automatic consequence of the

[90] See, *e.g., Pace University* v. *NLRB,* 514 F.3d 19, 23 (DC Cir. 2008); *Kearney & Trecker Corp.* v. *NLRB,* 209 F.2d 782, 786–88 (7th Cir. 1953).

Board's certification, the employer is legally bound to recognize and bargain with the certified representative. If the employer refuses to do so, it commits an unfair labor practice.[91] If such an employer is charged with a refusal to bargain, it is precluded from relitigating in the unfair labor practice proceeding any issues that were or could have been raised in the representation proceeding.[92] Finally, if such an employer seeks review of the Board's order in the unfair labor practice proceeding or the Board seeks to enforce its order in a court of appeals, the record from the representation proceeding must be filed with the court and ''the decree of the court enforcing, modifying, or setting aside in whole or in part the order of the Board shall be made and entered upon the pleadings, testimony, and proceedings set forth in such transcript.'' 29 U.S.C. 159(d); see also *Boire* v. *Greyhound Corp.* 376 U.S. 473, 477–79 (1964).[93]

Three limitations on the filing and posting requirements in the proposed amendments lead to the conclusion that they fall within the statutory exemption. First, the amendments impose requirements only on parties to the representation case proceeding, an administrative action or investigation against specific individuals or entities within the scope of section 3518(c)(1)(B)(ii). Second, any adverse consequences for failing to provide the requested information are imposed only on persons and entities that are party to the representation proceeding. Third, the possible adverse consequences that may result from noncompliance do not reach beyond the representation case proceeding. The proposed amendments impose no consequences on any party based on its failure to file or provide information requested in a petition or statement of position form other than to prevent the party from initiating a representation proceeding or to restrict a party's rights to raise issues or participate in the adjudication of issues in the specific representation proceeding and any related unfair labor practice proceeding. Similarly, as is the case currently,[94] no consequences attach to a failure to post either notice or to file the eligibility list beyond the overturning of an election conducted as part of the specific proceeding.

Sections 102.62(e), 102.63(a) and 102.67(i) of the proposed amendments require that an employer which is party to a representation proceeding post an Initial Notice to Employees of Election subsequent to the filing of a petition and, if an election is agreed to or directed, a Final Notice to Employees of Election. The Board will make available both notices to the employer in paper and electronic form, and employers will be permitted to post exact duplicate copies of the notices. The Board does not believe these posting requirements are subject to the PRA for the reasons explained above. Moreover, the Board does not believe that the notice posting requirements constitute a ''collection of information'' as defined in section 3502(3) of the PRA for an additional, independent reason. The notice posting requirements do not involve answers to questions or any form of reporting. Nor do they involve a ''recordkeeping requirement'' as that term is defined in section 3502(13) of the PRA. The proposed notice posting requirements do not require any party to ''maintain specified records.'' The Board notes that this construction is consistent with the Office of Management and Budget's regulations construing and implementing the PRA, which provide that ''[t]he public disclosure of information originally supplied by the Federal government to [a] recipient for the purpose of disclosure to the public'' is not considered a ''collection of information'' under the Act. See 5 CFR 1320.3(c)(2). For all of these reasons, the Board concludes that the posting requirements are not subject to the PRA.

Accordingly, the proposed amendments do not contain information collection requirements that require approval of the Office of Management and Budget under the Paperwork Reduction Act.

List of Subjects

29 CFR Part 101

Administrative practice and procedure, Labor management relations.

29 CFR Part 102

Administrative practice and procedure, Labor management relations.

29 CFR Part 103

Labor management relations.

In consideration of the foregoing, the National Labor Relations Board proposes to amend chapter I of title 29, Code of Federal Regulations, as follows:

PART 101—STATEMENTS OF PROCEDURES

1. The authority citation for part 101 continues to read as follows:

Authority: Sec. 6 of the National Labor Relations Act, as amended (29 U.S.C. 151, 156), and sec. 552(a) of the Administrative Procedure Act (5 U.S.C. 552(a)). Section 101.14 also issued under sec. 2112(a)(1) of Pub. L. 100–236, 28 U.S.C. 2112(a)(1).

Subpart C—[Removed and Reserved]

2. Remove and reserve subpart C, consisting of §§ 101.17 through 101.21.

Subpart D—[Removed and Reserved]

3. Remove and reserve subpart D, consisting of §§ 101.22 through 101.25.

Subpart E—[Removed and Reserved]

4. Remove and reserve subpart E, consisting of §§ 101.26 through 101.30.

PART 102—RULES AND REGULATIONS, SERIES 8

5. The authority citation for part 102 continues to read as follows:

Authority: Authority: Sections 1, 6, National Labor Relations Act (29 U.S.C. 151, 156). Section 102.117 also issued under section 552(a)(4)(A) of the Freedom of Information Act, as amended (5 U.S.C. 552(a)(4)(A)), and Section 102.117a also issued under section 552a(j) and (k) of the Privacy Act of 1974 (5 U.S.C. 552a(j) and (k)). Sections 102.143 through 102.155 also issued under section 504(c)(1) of the Equal Access to Justice Act, as amended (5 U.S.C. 504(c)(1)).

Subpart C—Procedure Under Section 9(c) of the Act for the Determination of Questions Concerning Representation of Employees And for Clarification of Bargaining Units and for Amendment of Certifications Under Section 9(b) of the Act

6. Revise § 102.60 to read as follows:

§ 102.60 Petitions.

(a) *Petition for certification or decertification.* A petition for investigation of a question concerning representation of employees under paragraphs (1)(A)(i) and (1)(B) of section 9(c) of the Act (hereinafter called a

[91] See, *e.g., Country Ford Trucks, Inc.* v. *NLRB,* 229 F.3d 1184, 1191 (DC Cir. 2000); *C.J. Krehbiel Co.* v. *NLRB,* 844 F.2d 880, 882, 886 (DC Cir. 1988).

[92] See *Pittsburgh Plate Glass Co.* v. *NLRB,* 313 U.S. 146, 162 (1941).

[93] Similarly, a union that has been certified or recognized as the representative of employees in an appropriate unit has a legal right to continue to be recognized as the exclusive representative of such employees. See *Scepter, Inc.* v. *NLRB,* 280 F.3d 1053, 1056 (DC Cir. 2002). However, if a petition is filed under section 9 seeking to decertify such a union, which is a party to the resulting representation proceeding, see *Brom Mach. & Foundry Co.* v. *NLRB,* 569 F.2d 1042, 1044 (8th Cir. 1978), and at the conclusion of the proceeding the Board certifies the results of an election finding that less than a majority of the voters cast ballots in favor of continued representation by the union, the union loses its legal right to represent the employees. *Retail Clerks Int'l Ass'n* v. *Montgomery Ward & Co.,* 316 F.2d 754, 756–57 (7th Cir. 1963).

[94] See John E. Higgins, Jr., The Developing Labor Law 595, 607 (5th ed. 2006) (noting that failure to provide *Excelsior* list or post notice of election constitutes grounds for setting aside election).

petition for certification) may be filed by an employee or group of employees or any individual or labor organization acting in their behalf or by an employer. A petition under paragraph (1)(A)(ii) of section 9(c) of the Act, alleging that the individual or labor organization which has been certified or is being currently recognized as the bargaining representative is no longer such representative (hereinafter called a petition for decertification), may be filed by any employee or group of employees or any individual or labor organization acting in their behalf. Petitions under this section shall be in writing and signed, and either shall be sworn to before a notary public, Board agent, or other person duly authorized by law to administer oaths and take acknowledgments or shall contain a declaration by the person signing it, under the penalty of perjury, that its contents are true and correct (see 28 U.S.C. 1746). One original of the petition shall be filed. A person filing a petition by facsimile or electronically pursuant to § 102.114(f) or (i) shall also file an original for the Agency's records, but failure to do so shall not affect the validity of the filing by facsimile or electronically, if otherwise proper. Except as provided in § 102.72, such petitions shall be filed with the regional director for the Region wherein the bargaining unit exists, or, if the bargaining unit exists in two or more Regions, with the regional director for any of such Regions with a certificate of service on all parties named in the petition. Along with the petition, the petitioner shall serve a description of procedures in representation cases and a Statement of Position form. Prior to the transfer of the record to the Board, the petition may be withdrawn only with the consent of the regional director with whom such petition was filed. After the transfer of the record to the Board, the petition may be withdrawn only with the consent of the Board. Whenever the regional director or the Board, as the case may be, approves the withdrawal of any petition, the case shall be closed.

(b) *Petition for clarification of bargaining unit or petition for amendment of certification.* A petition for clarification of an existing bargaining unit or a petition for amendment of certification, in the absence of a question concerning representation, may be filed by a labor organization or by an employer. Where applicable the same procedures set forth in paragraph (a) of this section shall be followed.

7. Revise § 102.61 to read as follows:

§ 102.61 Contents of petition for certification; contents of petition for decertification; contents of petition for clarification of bargaining unit; contents of petition for amendment of certification.

(a) *RC Petitions.* A petition for certification, when filed by an employee or group of employees or an individual or labor organization acting in their behalf, shall contain the following:

(1) The name of the employer.

(2) The address of the establishments involved.

(3) The general nature of the employer's business.

(4) A description of the bargaining unit which the petitioner claims to be appropriate.

(5) The names and addresses of any other persons or labor organizations who claim to represent any employees in the alleged appropriate unit, and brief descriptions of the contracts, if any, covering the employees in such unit.

(6) The number of employees in the alleged appropriate unit.

(7) A statement that a substantial number of employees in the described unit wish to be represented by the petitioner. Evidence supporting the statement shall be filed with the petition in accordance with paragraph (f) of this section, but shall not be served on any other party.

(8) A statement that the employer declines to recognize the petitioner as the representative within the meaning of section 9(a) of the Act or that the labor organization is currently recognized but desires certification under the act.

(9) The name, affiliation, if any, and address of the petitioner, and the name, title, address, telephone number, fax number, and e-mail address of the individual who will serve as the representative of the petitioner and accept service of all papers for purposes of the representation proceeding.

(10) Whether a strike or picketing is in progress at the establishment involved and, if so, the approximate number of employees participating, and the date such strike or picketing commenced.

(11) Any other relevant facts.

(b) *RM Petitions.* A petition for certification, when filed by an employer, shall contain the following:

(1) The name and address of the petitioner, and the name, title, address, telephone number, fax number, and e-mail address of the individual who will serve as the representative of the petitioner and accept service of all papers for purposes of the representation proceeding.

(2) The general nature of the petitioner's business.

(3) A brief statement setting forth that one or more individuals or labor organizations have presented to the petitioner a claim to be recognized as the exclusive representative of all employees in the unit claimed to be appropriate; a description of such unit; and the number of employees in the unit.

(4) The name or names, affiliation, if any, and addresses of the individuals or labor organizations making such claim for recognition.

(5) A statement whether the petitioner has contracts with any labor organization or other representatives of employees and, if so, their expiration date.

(6) Whether a strike or picketing is in progress at the establishment involved and, if so, the approximate number of employees participating, and the date such strike or picketing commenced.

(7) Any other relevant facts.

(8) Evidence supporting the statement that a labor organization has made a demand for recognition on the employer or that the employer has good faith uncertainty about majority support for an existing representative. Such evidence shall be filed together with the petition, but if the evidence reveals the names and/or number of employees who no longer wish to be represented, the evidence shall not be served on any other party. However, no proof of representation on the part of the labor organization claiming a majority is required and the regional director shall proceed with the case if other factors require it unless the labor organization withdraws its claim to majority representation.

(c) *RD Petitions.* Petitions for decertification shall contain the following:

(1) The name of the employer.

(2) The address of the establishments and a description of the bargaining unit involved.

(3) The general nature of the employer's business.

(4) The name and address of the petitioner and affiliation, if any, and the name, title, address, telephone number, fax number, and e-mail address of the individual who will serve as the representative of the petitioner and accept service of all papers for purposes of the representation proceeding.

(5) The name or names and addresses of the individuals or labor organizations who have been certified or are being currently recognized by the employer and who claim to represent any employees in the unit involved, and the expiration date of any contracts covering such employees.

(6) An allegation that the individuals or labor organizations who have been certified or are currently recognized by

the employer are no longer the representative in the appropriate unit as defined in section 9(a) of the Act.

(7) The number of employees in the unit.

(8) A statement that a substantial number of employees in the described unit no longer wish to be represented by the incumbent representative. Evidence supporting the statement shall be filed with the petition in accordance with paragraph (f) of this section, but shall not be served on any other party.

(9) Whether a strike or picketing is in progress at the establishment involved and, if so, the approximate number of employees participating, and the date such strike or picketing commenced.

(10) Any other relevant facts.

(d) *UC Petitions.* A petition for clarification shall contain the following:

(1) The name of the employer and the name of the recognized or certified bargaining representative.

(2) The address of the establishment involved.

(3) The general nature of the employer's business.

(4) A description of the present bargaining unit, and, if the bargaining unit is certified, an identification of the existing certification.

(5) A description of the proposed clarification.

(6) The names and addresses of any other persons or labor organizations who claim to represent any employees affected by the proposed clarifications, and brief descriptions of the contracts, if any, covering any such employees.

(7) The number of employees in the present bargaining unit and in the unit as proposed under the clarification.

(8) The job classifications of employees as to whom the issue is raised, and the number of employees in each classification.

(9) A statement by petitioner setting forth reasons why petitioner desires clarification of unit.

(10) The name, the affiliation, if any, and the address of the petitioner, and the name, title, address, telephone number, fax number, and e-mail address of the individual who will serve as the representative of the petitioner and accept service of all papers for purposes of the representation proceeding.

(11) Any other relevant facts.

(e) *AC Petitions.* A petition for amendment of certification shall contain the following:

(1) The name of the employer and the name of the certified union involved.

(2) The address of the establishment involved.

(3) The general nature of the employer's business.

(4) Identification and description of the existing certification.

(5) A statement by petitioner setting forth the details of the desired amendment and reasons therefor.

(6) The names and addresses of any other persons or labor organizations who claim to represent any employees in the unit covered by the certification and brief descriptions of the contracts, if any, covering the employees in such unit.

(7) The name, the affiliation, if any, and the address of the petitioner, and the name, title, address, telephone number, fax number, and e-mail address of the individual who will serve as the representative of the petitioner and accept service of all papers for purposes of the representation proceeding.

(8) Any other relevant facts.

(f) *Provision of original signatures.* Evidence filed pursuant to § 102.61(a)(7), (b)(8), or (c)(8) together with a petition that is filed by facsimile or electronically, which includes original signatures that cannot be transmitted in their original form by the method of filing of the petition, may be filed by facsimile or in electronic form provided that the original documents are received by the regional director no later than two days after the facsimile or electronic filing.

8. Revise § 102.62 to read as follows:

§ 102.62 Election agreements; voter list.

(a) *Consent election agreements with final regional director determinations of post-election disputes.* Where a petition has been duly filed, the employer and any individual or labor organizations representing a substantial number of employees involved may, with the approval of the regional director, enter into an agreement providing for the waiver of a hearing and for an election and further providing that post-election disputes will be resolved by the regional director. Such agreement, referred to as a consent election agreement, shall include a description of the appropriate unit, the time and place of holding the election, and the payroll period to be used in determining what employees within the appropriate unit shall be eligible to vote. Such election shall be conducted under the direction and supervision of the regional director. The method of conducting such election shall be consistent with the method followed by the regional director in conducting elections pursuant to §§ 102.69 and 102.70 except that the rulings and determinations by the regional director of the results thereof shall be final, and the regional director shall issue to the parties a certification of the results of the election, including certifications of representative where appropriate, with the same force and effect, in that case, as if issued by the Board, provided further that rulings or determinations by the regional director in respect to any amendment of such certification shall also be final.

(b) *Stipulated election agreements with discretionary board review.* Where a petition has been duly filed, the employer and any individuals or labor organizations representing a substantial number of the employees involved may, with the approval of the regional director, enter into an agreement providing for the waiver of a hearing and for an election as described in paragraph (a) of this section and further providing that the parties may request Board review of the regional director's resolution of post-election disputes. Such agreement, referred to as a stipulated election agreement, shall also include a description of the appropriate bargaining unit, the time and place of holding the election, and the payroll period to be used in determining which employees within the appropriate unit shall be eligible to vote. Such election shall be conducted under the direction and supervision of the regional director. The method of conducting such election and the post-election procedure shall be consistent with that followed by the regional director in conducting elections pursuant to §§ 102.69 and 102.70.

(c) *Full consent election agreements with final regional director determinations of pre- and post-election disputes.* Where a petition has been duly filed, the employer and any individual or labor organizations representing a substantial number of the employees involved may, with the approval of the regional director, enter into an agreement, referred to as a full consent election agreement, providing that pre- and post-election disputes will be resolved by the regional director. Such agreement provides for a hearing pursuant to §§ 102.63, 102.64, 102.65, 102.66 and 102.67 to determine if a question concerning representation exists. Upon the conclusion of such a hearing, the regional director shall issue a decision. The rulings and determinations by the regional director thereunder shall be final, with the same force and effect, in that case, as if issued by the Board. Any election ordered by the regional director shall be conducted under the direction and supervision of the regional director. The method of conducting such election shall be consistent with the method followed by the regional director in conducting elections pursuant to §§ 102.69 and 102.70, except that the rulings and determinations by the regional director of the results thereof shall be final, and the regional director shall issue to the

parties a certification of the results of the election, including certifications of representative where appropriate, with the same force and effect, in that case, as if issued by the Board, provided further that rulings or determinations by the regional director in respect to any amendment of such certification shall also be final.

(d) *Voter lists.* Absent agreement of the parties to the contrary specified in the election agreement or extraordinary circumstances specified in the direction, within two days after approval of an election agreement pursuant to paragraphs (a) or (b) of this section, or issuance of a direction of election pursuant to paragraph (c) of this section, the employer shall provide to the regional director and the parties named in the agreement or direction a list of the full names, home addresses, available telephone numbers, available e-mail addresses, work locations, shifts, and job classifications of all eligible voters. In order to be timely filed, the list must be received by the regional director and the parties named in the agreement or direction within two days after the approval of the agreement or issuance of the direction. The list of names shall be alphabetized (overall or by department) and be in an electronic format generally approved by the Board's Executive Secretary unless the employer certifies that it does not possess the capacity to produce the list in the required form. When feasible, the list shall be filed electronically with the regional director and served electronically on the other parties named in the petition. Failure to file or serve the list within the specified time and in proper format shall be grounds for setting aside the election whenever proper objections are filed. The regional director shall make the list available upon request to all parties in the case on the same day or as soon as practicable after the director receives the list from the employer. The parties shall use the list exclusively for purposes related to the representation proceeding and related Board proceedings.

(e) *Final notices to employees of election.* Upon approval of the election agreement pursuant to paragraphs (a) or (b) or with the direction of election pursuant to paragraph (c), the regional director shall promptly transmit the Board's Final Notice to Employees of Election to the parties by e-mail, facsimile, or by overnight mail (if neither an e-mail address nor facsimile number was provided). The regional director shall also electronically transmit the Final Notice to Employees of Election to affected employees to the extent practicable. The Final Notice to Employees of Election shall be posted in accordance with § 102.67(i).

9. Revise § 102.63 to read as follows:

§ 102.63 Investigation of petition by regional director; notice of hearing; service of notice; Initial Notice to Employees of Election; Statement of Position form; withdrawal of notice.

(a) *Investigations and notices.* (1) After a petition has been filed under § 102.61(a), (b), or (c), if no agreement such as that provided in § 102.62 is entered into and if it appears to the regional director that there is reasonable cause to believe that a question of representation affecting commerce exists, that the policies of the act will be effectuated, and that an election will reflect the free choice of employees in an appropriate unit, the regional director shall prepare and cause to be served upon the parties and upon any known individuals or labor organizations purporting to act as representatives of any employees directly affected by such investigation, a notice of hearing before a hearing officer at a time and place fixed therein. The regional director shall set the hearing for a date 7 days from the date of service of the notice absent special circumstances. A copy of the petition, a description of procedures in representation cases, an ''Initial Notice to Employees of Election'', and a Statement of Position form as described in paragraphs (b)(1) through (3) of this section, shall be served with such notice of hearing. Any such notice of hearing may be amended or withdrawn before the close of the hearing by the regional director on his own motion.

(2) The employer shall immediately post the Initial Notice to Employees of Election, where notices to employees are customarily posted, and shall also distribute it electronically if the employer customarily communicates with its employees electronically. The employer shall maintain the posting until the petition is dismissed or the Initial Notice is replaced by the Final Notice to Employees of Election. Failure to properly post and distribute the Initial Notice to Employees of Election shall be grounds for setting aside the results of the election whenever proper objections are filed.

(b)(1) *Statement of Position in RC cases.* After a petition has been filed under § 102.61(a) and the regional director has issued a notice of hearing, the employer shall file and serve on the parties named in the petition its Statement of Position by the date and in the manner specified in the notice unless that date is the same as the hearing date. If the Statement of Position is due on the date of the hearing, its completion shall be the first order of business at the hearing before any further evidence is received, and its completion may be accomplished with the assistance of the hearing officer.

(i) The employer's Statement of Position shall state whether the employer agrees that the Board has jurisdiction over the petition and provide the requested information concerning the employer's relation to interstate commerce; state whether the employer agrees that the proposed unit is appropriate, and, if the employer does not so agree, state the basis of the contention that the proposed unit is inappropriate, and describe the most similar unit that the employer concedes is appropriate; identify any individuals occupying classifications in the petitioned-for unit whose eligibility to vote the employer intends to contest at the pre-election hearing and the basis of each such contention; raise any election bar; state the employer's position concerning the type, dates, times, and location of the election and the eligibility period; and describe all other issues the employer intends to raise at the hearing.

(ii) The Statement of Position shall also state the name, title, address, telephone number, fax number, and e-mail address of the individual who will serve as the representative of the employer and accept service of all papers for purposes of the representation proceeding and be signed by a representative of the employer.

(iii) The Statement of Position shall further state the full names, work locations, shifts, and job classifications of all individuals in the proposed unit as of the payroll period preceding the filing of the petition who remain employed at the time of filing, and if the employer contends that the proposed unit is inappropriate, the employer shall also state the full names, work locations, shifts, and job classifications of all employees in the most similar unit that the employer concedes is appropriate. The list of names shall be alphabetized (overall or by department) and be in an electronic format generally approved by the Board's Executive Secretary unless the employer certifies that it does not possess the capacity to produce the list in the required form.

(iv) In addition to the information described in paragraph (b)(1)(iii) of this section, the lists filed with the regional director, but not served on any other party, shall contain available telephone numbers, available e-mail addresses, and home addresses of all individuals referred to in paragraph (b)(1)(iii) of this section.

(v) The employer shall be precluded from contesting the appropriateness of the petitioned-for unit at any time and from contesting the eligibility or inclusion of any individuals at the pre-election hearing, including by presenting evidence or argument, or by cross-examination of witnesses, if the employer fails to timely furnish the information described in paragraphs (b)(1)(iii) and (iv) of this section.

(2) *Statement of Position in RM cases.* If a petition has been filed under § 102.61(b), the individual or labor organization which is alleged to have presented to the petitioner a claim to be recognized shall file and serve on the regional director and the parties named in the petition its Statement of Position such that it is received by the regional director and the parties named in the petition on the date specified in the notice unless that date is the same as the hearing date. If the Statement of Position is due on the date of the hearing, its completion shall be the first order of business at the hearing before any further evidence is received, and its completion may be accomplished with the assistance of the hearing officer.

(i) *Individual or labor organization's Statement of Position.* The individual or labor organization's Statement of Position shall describe all issues the party intends to raise at the hearing.

(ii) *Identification of representative for service of papers.* The Statement of Position shall also state the name, title, address, telephone number, fax number, and e-mail address of the individual who will serve as the representative of the individual or labor organization and accept service of all papers for purposes of the representation proceeding and be signed by a representative of the individual or labor organization.

(iii) *Employer's Statement of Position.* Within the time permitted for filing the Statement of Position, the employer shall file with the regional director, and serve on the individual or labor organization, a list of the full names, work locations, shifts, and job classifications of all individuals in the proposed unit as of the payroll period preceding the filing of the petition who remain employed at the time of filing. The list of names shall be alphabetized (overall or by department) and be in an electronic format generally approved by the Board's Executive Secretary unless the employer certifies that it does not possess the capacity to produce the list in the required form.

(iv) *Contact information for individuals in proposed unit.* In addition to the information described in paragraph (b)(2)(iii) of this section, the lists filed with the regional director, but not served on any other party, shall contain the full names, available telephone numbers, available e-mail addresses, and home addresses of all individuals referred to in paragraph (b)(2)(iii) of this section.

(v) *Preclusion.* The employer shall be precluded from contesting the appropriateness of the unit at any time and from contesting the eligibility or inclusion of any individuals at the pre-election hearing, including by presenting evidence or argument, or by cross-examination of witnesses, if the employer fails to timely furnish the information described in paragraphs (b)(2)(iii) and (iv) of this section.

(3) *Statement of Position in RD cases.* If a petition has been filed under § 102.61(c), the employer and the certified or recognized representative of employees shall file and serve on the regional director and the parties named in the petition their respective Statements of Position such that they are received by the regional director and the parties named in the petition on the date specified in the notice unless that date is the same as the hearing date. If the Statements of Position are due on the date of the hearing, their completion shall be the first order of business at the hearing before any further evidence is received, and their completion may be accomplished with the assistance of the hearing officer.

(i) The Statements of Position of the employer and the certified or recognized representative shall describe all issues each party intends to raise at the hearing.

(ii) The Statements of Position shall also state the name, title, address, telephone number, fax number, and e-mail address of the individual who will serve as the representative of the employer or the certified or recognized representative of the employees and accept service of all papers for purposes of the representation proceeding and be signed by a representative of the employer or the certified or recognized representative, respectively.

(iii) The employer's Statement of Position shall also state the full names, work locations, shifts, and job classifications of all individuals in the proposed unit as of the payroll period preceding the filing of the petition who remain employed at the time of filing, and if the employer contends that the proposed unit is inappropriate, the employer shall also state the full names, work locations, shifts, and job classifications of all individuals in the certified or recognized unit. The list of names shall be alphabetized (overall or by department) and be in an electronic format generally approved by the Board's Executive Secretary unless the employer certifies that it does not possess the capacity to produce the list in the required form.

(iv) In addition to the information described in paragraph (b)(3)(iii) of this section, the lists filed with the regional director, but not served on any other party, shall contain the full names, available telephone numbers, available e-mail addresses, and home addresses of all individuals referred to in paragraph (b)(3)(iii) of this section.

(v) The employer shall be precluded from contesting the appropriateness of the petitioned-for unit at any time and from contesting the eligibility or inclusion of any individuals at the pre-election hearing, including by presenting evidence or argument, or by cross-examination of witnesses, if the employer fails to timely furnish the information described in paragraphs (b)(3)(iii) and (b)(3)(iv) of this section.

(c) *UC or AC cases.* After a petition has been filed under § 102.61(d) or (e), the regional director shall conduct an investigation and, as appropriate, he may issue a decision without a hearing; or prepare and cause to be served upon the parties and upon any known individuals or labor organizations purporting to act as representatives of any employees directly affected by such investigation, a notice of hearing before a hearing officer at a time and place fixed therein; or take other appropriate action. If a notice of hearing is served, it shall be accompanied by a copy of the petition. Any such notice of hearing may be amended or withdrawn before the close of the hearing by the regional director on his own motion. All hearing and posthearing procedure under paragraph (c) of this section shall be in conformance with §§ 102.64 through 102.69 whenever applicable, except where the unit or certification involved arises out of an agreement as provided in § 102.62(a), the regional director's action shall be final, and the provisions for review of regional director's decisions by the Board shall not apply. Dismissals of petitions without a hearing shall not be governed by § 102.71. The regional director's dismissal shall be by decision, and a request for review therefrom may be obtained under § 102.67, except where an agreement under § 102.62(a) is involved.

10. Revise § 102.64 to read as follows:

§ 102.64 Conduct of hearing.

(a) The purpose of a hearing conducted under section 9(c) of the Act is to determine if a question of representation exists. A question of representation exists if a petition as

described in section 9(c) of the Act has been filed concerning a unit appropriate for the purpose of collective bargaining or, in the case of a petition filed under section 9(c)(1)(A)(ii), concerning a unit in which an individual or labor organization has been certified or is being currently recognized by the employer as the bargaining representative. If, upon the record of the hearing, the regional director finds that such a question of representation exists and there is no bar to an election, he shall direct an election to resolve the question and, subsequent to that election, unless specifically provided otherwise in these rules, resolve any disputes concerning the eligibility or inclusion of voters that might affect the results of the election.

(b) Hearings shall be conducted by a hearing officer and shall be open to the public unless otherwise ordered by the hearing officer. At any time, a hearing officer may be substituted for the hearing officer previously presiding. Subject to the provisions of § 102.66, it shall be the duty of the hearing officer to inquire fully into all genuine disputes as to material facts in order to obtain a full and complete record upon which the Board or the regional director may discharge their duties under section 9(c) of the Act.

(c) The hearing officer shall continue the hearing from day to day until completed absent extraordinary circumstances.

11. Revise § 102.65 to read as follows:

§ 102.65 Motions; interventions.

(a) All motions, including motions for intervention pursuant to paragraphs (b) and (e) of this section, shall be in writing or, if made at the hearing, may be stated orally on the record and shall briefly state the order or relief sought and the grounds for such motion. An original and two copies of written motions shall be filed and a copy thereof immediately shall be served on the other parties to the proceeding. Motions made prior to the transfer of the record to the Board shall be filed with the regional director, except that motions made during the hearing shall be filed with the hearing officer. After the transfer of the record to the Board, all motions shall be filed with the Board. Such motions shall be printed or otherwise legibly duplicated. Eight copies of such motions shall be filed with the Board. The regional director may rule upon all motions filed with him, causing a copy of said ruling to be served on the parties, or he may refer the motion to the hearing officer: *Provided,* That if the regional director prior to the close of the hearing grants a motion to dismiss the petition, the petitioner may obtain a review of such ruling in the manner prescribed in § 102.71. The hearing officer shall rule, either orally on the record or in writing, upon all motions filed at the hearing or referred to him as hereinabove provided, except that all motions to dismiss petitions shall be referred for appropriate action at such time as the entire record is considered by the regional director or the Board, as the case may be.

(b) Any person desiring to intervene in any proceeding shall make a motion for intervention, stating the grounds upon which such person claims to have an interest in the proceeding. The regional director or the hearing officer, as the case may be, may by order permit intervention in person or by counsel or other representative to such extent and upon such terms as he may deem proper, and such intervenor shall thereupon become a party to the proceeding. Any person desiring to intervene in any such proceeding shall also complete a Statement of Position form.

(c) All motions, rulings, and orders shall become a part of the record, except that rulings on motions to revoke subpoenas shall become a part of the record only upon the request of the party aggrieved thereby as provided in § 102.66(g). Unless expressly authorized by the Rules and Regulations, rulings by the regional director or by the hearing officer shall not be appealed directly to the Board, but shall be considered by the Board on appropriate request for review pursuant to § 102.67 (b), (c), and (d) or § 102.69. Nor shall rulings by the hearing officer be appealed directly to the regional director unless expressly authorized by the Rules and Regulations, except by special permission of the regional director, but shall be considered by the regional director when he reviews the entire record. Requests to the regional director, or to the Board in appropriate cases, for special permission to appeal from a ruling of the hearing officer or the regional director, together with the appeal from such ruling, shall be filed promptly, in writing, and shall briefly state the reasons special permission should be granted, including why the issue will otherwise evade review, and the grounds relied on for the appeal. The moving party shall immediately serve a copy of the request for special permission and of the appeal on the other parties and on the regional director. Any statement in opposition or other response to the request and/or to the appeal shall be filed promptly, in writing, and shall be served immediately on the other parties and on the regional director. Neither the Board nor the regional director will grant a request for special permission to appeal except in extraordinary circumstances where it appears that the issue will otherwise evade review. No party shall be precluded from raising an issue at a later time based on its failure to seek special permission to appeal. If the Board or the regional director, as the case may be, grants the request for special permission to appeal, the Board or the regional director may proceed forthwith to rule on the appeal. Neither the filing nor the grant of such a request shall, unless otherwise ordered by the Board, operate as a stay of an election or any action taken or directed by the regional director. Notwithstanding a pending request for special permission to appeal, the regional director shall not impound ballots cast in an election unless otherwise ordered by the Board.

(d) The right to make motions or to make objections to rulings on motions shall not be deemed waived by participation in the proceeding.

(e)(1) A party to a proceeding may, because of extraordinary circumstances, move after the close of the hearing for reopening of the record, or move after the decision or report for reconsideration, for rehearing, or to reopen the record, but no such motion shall stay the time for filing a request for review of a decision or exceptions to a report. No motion for reconsideration, for rehearing, or to reopen the record will be entertained by the Board or by any regional director or hearing officer with respect to any matter which could have been but was not raised pursuant to any other section of these rules: *Provided, however,* That the regional director may treat a request for review of a decision or exceptions to a report as a motion for reconsideration. A motion for reconsideration shall state with particularity the material error claimed and with respect to any finding of material fact shall specify the page of the record relied on for the motion. A motion for rehearing or to reopen the record shall specify briefly the error alleged to require a rehearing or hearing *de novo,* the prejudice to the movant alleged to result from such error, the additional evidence sought to be adduced, why it was not presented previously, and what result it would require if adduced and credited. Only newly discovered evidence—evidence which has become available only since the close of the hearing—or evidence which the regional director or the Board believes should have been taken at the hearing will be taken at any further hearing.

(2) Any motion for reconsideration or for rehearing pursuant to this paragraph (e) shall be filed within 14 days, or such further period as may be allowed, after the service of the decision or report. Any request for an extension of time to file such a motion shall be served promptly on the other parties. A motion to reopen the record shall be filed promptly on discovery of the evidence sought to be adduced.

(3) The filing and pendency of a motion under this provision shall not unless so ordered operate to stay the effectiveness of any action taken or directed to be taken nor will a regional director or the Board delay any decision or action during the period specified in paragraph (e)(2) of this section, except that, if a motion for reconsideration based on changed circumstances or to reopen the record based on newly discovered evidence states with particularity that the granting thereof will affect the eligibility to vote of specific employees, the Board agent shall have discretion to allow such employees to vote subject to challenge even if they are specifically excluded in the direction of election and to permit the moving party to challenge the ballots of such employees even if they are specifically included in the direction of election in any election conducted while such motion is pending. A motion for reconsideration, for rehearing, or to reopen the record need not be filed to exhaust administrative remedies.

12. Revise § 102.66 to read as follows:

§ 102.66 Introduction of evidence: Rights of parties at hearing; subpoenas.

(a) *Rights of parties at hearing.* Any party shall have the right to appear at any hearing in person, by counsel, or by other representative, and any party and the hearing officer shall have power to call, examine, and cross-examine witnesses and to introduce into the record documentary and other evidence relevant to any genuine dispute as to a material fact. The hearing officer shall identify such disputes as follows:

(1) *Joinder in RC cases.* In a case arising under § 102.61(a), after the employer completes its Statement of Position and prior to the introduction of further evidence, the petitioner shall respond to each issue raised in the Statement. The hearing officer shall not receive evidence relevant to any issue concerning which parties have not taken adverse positions: *Provided, however,* That if the employer fails to take a position regarding the appropriateness of the petitioned-for unit, the petitioner shall explain why the proposed unit is appropriate and may support its explanation with evidence in the form of sworn statements or declarations consistent with the requirements stated in § 102.60(a) or through examination of witnesses and introduction of documentary or other evidence.

(2) *Joinder in RM cases.* In a case arising under § 102.61(b), after the individual or labor organization completes its Statement of Position and prior to the introduction of further evidence, the petitioner shall respond to each issue raised in the Statement. The hearing officer shall not receive evidence relevant to any issue concerning which parties have not taken adverse positions: *Provided, however,* That if the individual or labor organization fails to take a position regarding the appropriateness of the petitioned-for unit, the petitioner shall explain why the proposed unit is appropriate and may support its explanation with evidence in the form of sworn statements or declarations consistent with the requirements stated in § 102.60(a) or through examination of witnesses and introduction of documentary or other evidence.

(3) *Joinder in RD cases.* In a case arising under § 102.61(c), after the employer and the certified or recognized representative of employees complete their respective Statements of Position and prior to the introduction of further evidence, the petitioner shall respond to each issue raised in the Statements. The hearing officer shall not receive evidence relevant to any issue concerning which parties have not taken adverse positions: *Provided, however,* That if the employer and/or the certified or recognized representative fails to take a position regarding whether the petitioned-for unit is coextensive with the unit for which a representative is certified or recognized, the petitioner shall explain why the proposed unit is appropriate and may support its explanation with evidence in the form of sworn statements or declarations consistent with the requirements stated in § 102.60(a) or through examination of witnesses and introduction of documentary or other evidence.

(b) *Offers of proof; discussion of election procedure.* After identifying the issues in dispute pursuant to paragraph (a) of this section, the hearing officer shall solicit offers of proof from the parties or their counsel as to all such issues. The offers of proof shall take the form of a written statement or an oral statement on the record identifying each witness the party would call to testify concerning the issue and summarizing the witness' testimony. The hearing officer shall examine the offers of proof related to each issue in dispute and shall proceed to hear testimony and accept other evidence relevant to the issue only if the offers of proof raise a genuine dispute as to any material fact. Prior to the close of the hearing, the hearing officer will:

(1) Solicit the parties' positions on the type, dates, times, and locations of the election and the eligibility period, but shall not permit litigation of those issues;

(2) Inform the parties that the regional director will issue a decision, direction of election or both as soon as practicable and that the director will immediately transmit the document(s) to the parties' designated representatives by e-mail, facsimile, or by overnight mail (if neither an e-mail address nor facsimile number was provided); and

(3) Inform the parties what their obligations will be under these rules if the director directs an election and of the time for complying with such obligations.

(c) *Preclusion.* A party shall be precluded from raising any issue, presenting any evidence relating to any issue, cross-examining any witness concerning any issue, and presenting argument concerning any issue that the party failed to raise in its timely Statement of Position or to place in dispute in response to another party's Statement: *Provided, however,* that no party shall be precluded from contesting or presenting evidence relevant to the Board's statutory jurisdiction to process the petition; *Provided, further,* that no party shall be precluded, on the grounds that a voter's eligibility or inclusion was not contested at the pre-election hearing, from challenging the eligibility of any voter during the election. If a party contends that the petitioned-for unit is not appropriate in its Statement of Position but fails to state the most similar unit that it concedes is appropriate, the party shall also be precluded from raising any issue as to the appropriateness of the unit, presenting any evidence relating to the appropriateness of the unit, cross-examining any witness concerning the appropriateness of the unit, and presenting argument concerning the appropriateness of the unit.

(d) *Disputes concerning less than 20 percent of the unit.* If at any time during the hearing, the hearing officer determines that the only issues remaining in dispute concern the eligibility or inclusion of individuals who would constitute less than 20 percent of the unit if they were found to be eligible to vote, the hearing officer shall close the hearing.

(e) *Witness examination and evidence.* Witnesses shall be examined

orally under oath. The rules of evidence prevailing in courts of law or equity shall not be controlling. Stipulations of fact may be introduced in evidence with respect to any issue.

(f) *Objections.* Any objection with respect to the conduct of the hearing, including any objection to the introduction of evidence, may be stated orally or in writing, accompanied by a short statement of the grounds of such objection, and included in the record. No such objection shall be deemed waived by further participation in the hearing.

(g) *Subpoenas.* The Board, or any Member thereof, shall, on the written application of any party, forthwith issue subpoenas requiring the attendance and testimony of witnesses and the production of any evidence, including books, records, correspondence, or documents, in their possession or under their control. The Executive Secretary shall have the authority to sign and issue any such subpoenas on behalf of the Board or any Member thereof. Any party may file applications for subpoenas in writing with the regional director if made prior to hearing, or with the hearing officer if made at the hearing. Applications for subpoenas may be made ex parte. The regional director or the hearing officer, as the case may be, shall forthwith grant the subpoenas requested. Any person served with a subpoena, whether ad testificandum or duces tecum, if he or she does not intend to comply with the subpoena, shall, within 5 days after the date of service of the subpoena or by such earlier time as the hearing officer or regional director shall determine, petition in writing to revoke the subpoena. The date of service for purposes of computing the time for filing a petition to revoke shall be the date the subpoena is received. Such petition shall be filed with the regional director who may either rule upon it or refer it for ruling to the hearing officer: *Provided, however,* That if the evidence called for is to be produced at a hearing and the hearing has opened, the petition to revoke shall be filed with the hearing officer or, with the permission of the hearing officer, presented orally. Notice of the filing of petitions to revoke shall be promptly given by the regional director or hearing officer, as the case may be, to the party at whose request the subpoena was issued. The regional director or the hearing officer, as the case may be, shall revoke the subpoena if, in his opinion, the evidence whose production is required does not relate to any matter under investigation or in question in the proceedings or the subpoena does not describe with sufficient particularity the evidence whose production is required, or if for any other reason sufficient in law the subpoena is otherwise invalid. The regional director or the hearing officer, as the case may be, shall make a simple statement of procedural or other grounds for his ruling. The petition to revoke, any answer filed thereto, and any ruling thereon shall not become part of the record except upon the request of the party aggrieved by the ruling. Persons compelled to submit data or evidence are entitled to retain or, on payment of lawfully prescribed costs, to procure copies or transcripts of the data or evidence submitted by them.

(h) *Oral argument and briefs.* Any party shall be entitled, upon request, to a reasonable period at the close of the hearing for oral argument, which shall be included in the stenographic report of the hearing. Briefs shall be filed only upon special permission of the hearing officer and within the time the hearing officer permits.

(i) *Hearing officer analysis.* The hearing officer may submit an analysis of the record to the regional director but he shall make no recommendations.

(j) *Witness fees.* Witness fees and mileage shall be paid by the party at whose instance the witness appears.

13. Revise § 102.67 to read as follows:

§ 102.67 Proceedings before the regional director; further hearing; action by the regional director; review of action by the regional director; statement in opposition; final notice of election; voter list.

(a) *Proceedings before regional director.* The regional director may proceed, either forthwith upon the record or after oral argument, the submission of briefs, or further hearing, as he may deem proper, to determine whether a question concerning representation exists in a unit appropriate for purposes of collective bargaining, and to direct an election, dismiss the petition, or make other disposition of the matter. If the hearing officer has determined during the hearing or the regional director determines after the hearing that the only issues remaining in dispute concern the eligibility or inclusion of individuals who would constitute less than 20 percent of the unit if they were found to be eligible to vote, the regional director shall direct that those individuals be permitted to vote subject to challenge. In the event that the regional director permits individuals whose eligibility or inclusion remains in dispute to vote subject to challenge, the Final Notice to Employees of Election shall advise employees that said individuals are neither included in, nor excluded from, the bargaining unit, inasmuch as the regional director has permitted them to vote subject to challenge. The election notice shall further advise employees that the eligibility or inclusion of said individuals will be resolved, if necessary, following the election.

(b) *Directions of elections; dismissals; requests for review.* A decision by the regional director upon the record shall set forth his findings, conclusions, and order or direction: *Provided, however,* that the regional director may direct an election with findings and a statement of reasons to follow prior to the tally of ballots. In the event that the regional director directs an election, said direction shall specify the type, date, time, and place of the election and the eligibility period. The regional director shall schedule the election for the earliest date practicable consistent with these rules. The regional director shall transmit the direction of election to the parties' designated representatives by e-mail, facsimile, or by overnight mail (if neither an e-mail address nor facsimile number was provided). Along with the direction of election, the regional director shall also transmit the Board's Final Notice to Employees of Election by e-mail, facsimile, or by overnight mail (if neither an e-mail address nor facsimile number was provided). The regional director shall also electronically transmit the Final Notice to Employees of Election to affected employees to the extent practicable. The decision of the regional director shall be final: *Provided, however,* That within 14 days after service of a decision dismissing a petition any party may file a request for review of such a dismissal with the Board in Washington, DC: *Provided, further,* That any party may, after the election, file a request for review of a regional director's decision to direct an election within the time periods specified and as described in § 102.69.

(c) *Grounds for review.* The Board will grant a request for review only where compelling reasons exist therefor. Accordingly, a request for review may be granted only upon one or more of the following grounds:

(1) That a substantial question of law or policy is raised because of:

(i) The absence of, or

(ii) A departure from, officially reported Board precedent.

(2) That the regional director's decision on a substantial factual issue is clearly erroneous on the record and such error prejudicially affects the rights of a party.

(3) That the conduct of the hearing or any ruling made in connection with the

proceeding has resulted in prejudicial error.

(4) That there are compelling reasons for reconsideration of an important Board rule or policy.

(d) *Contents of request.* Any request for review must be a self-contained document enabling the Board to rule on the basis of its contents without the necessity or recourse to the record; however, the Board may, in its discretion, examine the record in evaluating the request. With respect to the ground listed in paragraph (c)(2) of this section, and other grounds where appropriate, said request must contain a summary of all evidence or rulings bearing on the issues together with page citations from the transcript and a summary of argument. But such request may not raise any issue or allege any facts not timely presented to the regional director.

(e) *Opposition to request.* Any party may, within 7 days after the last day on which the request for review must be filed, file with the Board a statement in opposition thereto, which shall be served in accordance with the requirements of paragraph (h) of this section. A statement of such service of opposition shall be filed simultaneously with the Board. The Board may deny the request for review without awaiting a statement in opposition thereto.

(f) *Waiver; denial of request.* The parties may, at any time, waive their right to request review. Failure to request review shall preclude such parties from relitigating, in any related subsequent unfair labor practice proceeding, any issue which was, or could have been, raised in the representation proceeding. Denial of a request for review shall constitute an affirmance of the regional director's action which shall also preclude relitigating any such issues in any related subsequent unfair labor practice proceeding.

(g) *Grant of review; briefs.* The granting of a request for review shall not stay the regional director's decision unless otherwise ordered by the Board. Except where the Board rules upon the issues on review in the order granting review, the appellants and other parties may, within 14 days after issuance of an order granting review, file briefs with the Board. Such briefs may be reproductions of those previously filed with the regional director and/or other briefs which shall be limited to the issues raised in the request for review. Where review has been granted, the Board will consider the entire record in the light of the grounds relied on for review. Any request for review may be withdrawn with the permission of the Board at any time prior to the issuance of the decision of the Board thereon.

(h)(1) *Format of request.* All documents filed with the Board under the provisions of this section shall be filed in seven copies, double spaced, on 8½ by 11-inch paper, and shall be printed or otherwise legibly duplicated. Requests for review, including briefs in support thereof; statements in opposition thereto; and briefs on review shall not exceed 50 pages in length, exclusive of subject index and table of cases and other authorities cited, unless permission to exceed that limit is obtained from the Board by motion, setting forth the reasons therefor, filed not less than 5 days, including Saturdays, Sundays, and holidays, prior to the date the document is due. Where any brief filed pursuant to this section exceeds 20 pages, it shall contain a subject index with page authorities cited.

(2) *Service of copies of request.* The party filing with the Board a request for review, a statement in opposition to a request for review, or a brief on review shall serve a copy thereof on the other parties and shall file a copy with the regional director. A statement of such service shall be filed with the Board together with the document.

(3) *Extensions.* Requests for extensions of time to file requests for review, statements in opposition to a request for review, or briefs, as permitted by this section, shall be filed with the Board or the regional director, as the case may be. The party filing the request for an extension of time shall serve a copy thereof on the other parties and, if filed with the Board, on the regional director. A statement of such service shall be filed with the document.

(i) *Final notice to employees of election.* The employer shall post copies of the Board's Final Notice to Employees of Election in conspicuous places at least 2 full working days prior to 12:01 a.m. of the day of the election and shall also distribute the Final Notice to Employees of Election electronically if the employer customarily communicates with employees in the unit electronically. In elections involving mail ballots, the election shall be deemed to have commenced the day the ballots are deposited by the regional office in the mail. In all cases, the notices shall remain posted until the end of the election. The term working day shall mean an entire 24-hour period excluding Saturdays, Sundays, and holidays. A party shall be estopped from objecting to nonposting of notices if it is responsible for the nonposting. Failure properly to post and distribute the election notices as required herein shall be grounds for setting aside the election whenever proper and timely objections are filed under the provisions of § 102.69(a).

(j) *Voter lists.* Absent extraordinary circumstances specified in the direction of election, the employer shall, within 2 days after such direction, provide to the regional director and the parties named in such direction a list of the full names, home addresses, available telephone numbers, available e-mail addresses, work locations, shifts, and job classifications of all eligible voters. In order to be timely filed, the list must be received by the regional director and the parties named in the direction within 2 days of the direction of election unless a longer time is specified therein. The list of names shall be alphabetized (overall or by department) and be in an electronic format generally approved by the Board's Executive Secretary unless the employer certifies that it does not possess the capacity to produce the list in the required form. When feasible, the list shall be filed electronically with the regional director and served electronically on the other parties named in the petition. Failure to file or serve the list within the specified time and in proper format shall be grounds for setting aside the election whenever proper objections are filed. The regional director shall make the list available upon request to all parties in the case on the same day or as soon as practicable after the director receives the list from the employer. The parties shall use the list exclusively for purposes of the representation proceeding and related Board proceedings.

14. Revise § 102.68 to read as follows:

§ 102.68 Record; what constitutes; transmission to Board.

The record in a proceeding conducted pursuant to the foregoing section, or conducted pursuant to § 102.69, shall consist of: The petition, notice of hearing with affidavit of service thereof, Statements of Position, motions, rulings, orders, the stenographic report of the hearing and of any oral argument before the regional director, stipulations, exhibits, affidavits of service, and any briefs or other legal memoranda submitted by the parties to the regional director or to the Board, and the decision of the regional director, if any. Immediately upon issuance of an order granting a request for review by the Board, the regional director shall transmit the record to the Board.

15. Revise § 102.69 to read as follows:

§ 102.69 Election procedure; tally of ballots; objections; requests for review of directions of elections, hearings; hearing officer reports on objections and challenges; exceptions to hearing officer reports; requests for review of regional director reports or decisions in stipulated or directed elections.

(a) *Election procedure; tally; objections.* Unless otherwise directed by the Board, all elections shall be conducted under the supervision of the regional director in whose Region the proceeding is pending. All elections shall be by secret ballot. Whenever two or more labor organizations are included as choices in an election, either participant may, upon its prompt request to and approval thereof by the regional director, whose decision shall be final, have its name removed from the ballot: *Provided, however,* That in a proceeding involving an employer-filed petition or a petition for decertification the labor organization certified, currently recognized, or found to be seeking recognition may not have its name removed from the ballot without giving timely notice in writing to all parties and the regional director, disclaiming any representation interest among the employees in the unit. A pre-election conference may be held at which the parties may check the list of voters and attempt to resolve any questions of eligibility or inclusions in the unit. When the election is conducted manually, any party may be represented by observers of its own selection, subject to such limitations as the regional director may prescribe. Any party and Board agents may challenge, for good cause, the eligibility of any person to participate in the election. The ballots of such challenged persons shall be impounded. Upon the conclusion of the election the ballots will be counted and a tally of ballots prepared and immediately made available to the parties. Within 7 days after the tally of ballots has been prepared, any party may file with the regional director an original and five copies of objections to the conduct of the election or to conduct affecting the results of the election with a certificate of service on all parties, which shall contain a short statement of the reasons therefore and a written offer of proof in the form described in § 102.66(b) insofar as applicable, but the written offer of proof shall not be served on any other party. Such filing must be timely whether or not the challenged ballots are sufficient in number to affect the results of the election. A person filing objections by facsimile or electronically pursuant to § 102.114(f) or (i) shall also file an original for the Agency's records, but failure to do so shall not affect the validity of the filing if otherwise proper. In addition, extra copies need not be filed if the filing is by facsimile or electronically pursuant to § 102.114(f) or (i).

(b) *Requests for review of directions of elections.* If the election has been conducted pursuant to § 102.67, any party may file a request for review of the decision and direction of election with the Board in Washington, DC. In the absence of election objections or potentially determinative challenges, the request for review of the decision and direction of election shall be filed within 14 days after the tally of ballots has been prepared. In a case involving election objections or potentially determinative challenges, the request for review shall be filed within 14 days after the regional director's report or supplemental decision on challenged ballots, on objections, or on both, and may be combined with a request for review of that decision as provided in paragraph (d)(3) of this section. The procedures for such request for review shall be the same as set forth in § 102.67(c) through (h) insofar as applicable. If no request for review is filed, the decision and direction of election is final and shall have the same effect as if issued by the Board. The parties may, at any time, waive their right to request review. Failure to request review shall preclude such parties from relitigating, in any related subsequent unfair labor practice proceeding, any issue which was, or could have been, raised in the representation proceeding. Denial of a request for review shall constitute an affirmance of the regional director's action which shall also preclude relitigating any such issues in any related subsequent unfair labor practice proceeding.

(c) *Certification in the absence of objections, determinative challenges and requests for review.* If no objections are filed within the time set forth in paragraph (a) of this section, if the challenged ballots are insufficient in number to affect the results of the election, if no runoff election is to be held pursuant to § 102.70, and if no request for review is filed pursuant to paragraph (b) of this section, the regional director shall forthwith issue to the parties a certification of the results of the election, including certification of representative where appropriate, with the same force and effect as if issued by the Board, and the proceeding will thereupon be closed.

(d)(1)(i) *Reports.* If timely objections are filed to the conduct of an election or to conduct affecting the results of the election, and the regional director determines that the evidence described in the accompanying offer of proof would not constitute grounds for overturning the election if introduced at a hearing, the regional director shall issue a report or supplemental decision disposing of objections and a certification of the results of the election, including certification of representative where appropriate, unless there are potentially determinative challenges.

(ii) *Notices of hearing.* If timely objections are filed to the conduct of the election or to conduct affecting the results of the election, and the regional director determines that the evidence described in the accompanying offer of proof could be grounds for overturning the election if introduced at a hearing, or if the challenged ballots are sufficient in number to affect the results of the election, the regional director shall transmit to the parties' designated representatives by e-mail, facsimile, or by overnight mail (if neither an e-mail address nor facsimile number was provided) a notice of hearing before a hearing officer at a place and time fixed therein no later than 14 days after the preparation of the tally of ballots or as soon as practicable thereafter: *Provided, however,* that the regional director may consolidate the hearing concerning objections and determinative challenges with an unfair labor practice proceeding before an administrative law judge.

(iii) *Hearings; hearing officer reports; exceptions to regional director.* Any hearing pursuant to this section shall be conducted in accordance with the provisions of §§ 102.64, 102.65, and 102.66, insofar as applicable, except that, upon the close of such hearing, the hearing officer shall prepare and cause to be served on the parties a report resolving questions of credibility and containing findings of fact and recommendations as to the disposition of the issues. Any party may, within 14 days from the date of issuance of such report, file with the regional director an original and one copy of exceptions to such report, with supporting brief if desired. A copy of such exceptions, together with a copy of any brief filed, shall immediately be served on the other parties and a statement of service filed with the regional director. Within 7 days from the last date on which exceptions and any supporting brief may be filed, or such further time as the regional director may allow, a party opposing the exceptions may file an answering brief with the regional director. An original and one copy shall be submitted. A copy of such answering brief shall immediately be served on the

other parties and a statement of service filed with the regional director. If no exceptions are filed to such report, the regional director, upon the expiration of the period for filing such exceptions, may decide the matter forthwith upon the record or may make other disposition of the case.

(2) *Regional director reports or decisions in consent or full consent elections.* If the election has been held pursuant to § 102.62(a) or (c), the report or decision of the regional director shall be final and shall include a certification of the results of the election, including certification of representative where appropriate.

(3) *Requests for review of regional director reports or decisions in stipulated or directed elections.* If the election has been held pursuant to §§ 102.62(b) or 102.67, within 14 days from the date of issuance of the regional director's report or decision on challenged ballots or on objections, or on both, any party may file with the Board in Washington, DC, a request for review of such report or decision which may be combined with a request for review of the regional director's decision to direct an election as provided in § 102.67(b). The procedures for post-election requests for review shall be the same as set forth in § 102.67(c) through (h) insofar as applicable. If no request for review is filed, the report or decision is final and shall have the same effect as if issued by the Board. The parties may, at any time, waive their right to request review. Failure to request review shall preclude such parties from relitigating, in any related subsequent unfair labor practice proceeding, any issue which was, or could have been, raised in the representation proceeding. Denial of a request for review shall constitute an affirmance of the regional director's action which shall also preclude relitigating any such issues in any related subsequent unfair labor practice proceeding. *Provided, however,* that in any proceeding wherein a representation case has been consolidated with an unfair labor practice proceeding for purposes of hearing the provisions of § 102.46 shall govern with respect to the filing of exceptions or an answering brief to the exceptions to the administrative law judge's decision.

(e)(1)(i) *Record in case with hearing.* In a proceeding pursuant to this section in which a hearing is held, the record in the case shall consist of the notice of hearing, motions, rulings, orders, stenographic report of the hearing, stipulations, exhibits, together with the objections to the conduct of the election or to conduct affecting the results of the election, offers of proof, any briefs or other legal memoranda submitted by the parties, any report on such objections and/or on challenged ballots, exceptions, the decision of the regional director, any requests for review, and the record previously made as defined in § 102.68. Materials other than those set out above shall not be a part of the record.

(ii) *Record in case with no hearing.* In a proceeding pursuant to this section in which no hearing is held, the record shall consist of the objections to the conduct of the election or to conduct affecting the results of the election, any report or decision on objections or on challenged ballots and any request for review of such a report or decision, any documentary evidence, excluding statements of witnesses, relied upon by the regional director in his decision or report, any briefs or other legal memoranda submitted by the parties, and any other motions, rulings or orders of the regional director. Materials other than those set out above shall not be a part of the record, except as provided in paragraph (e)(3) of this section.

(2) Immediately upon issuance of an order granting a request for review by the Board, the regional director shall transmit to the Board the record of the proceeding as defined in paragraph (e)(1) of this section.

(3) In a proceeding pursuant to this section in which no hearing is held, a party filing a request for review of a regional director's report or decision on objections, or any opposition thereto, may support its submission to the Board by appending thereto copies of any offer of proof, including copies of any affidavits or other documentary evidence, it has timely submitted to the regional director and which were not included in the report or decision. Documentary evidence so appended shall thereupon become part of the record in the proceeding. Failure to append that evidence to its submission to the Board in the representation proceeding as provided above, shall preclude a party from relying on such evidence in any subsequent unfair labor proceeding.

(f) *Revised tally of ballots.* In any case under this section in which the regional director, upon a ruling on challenged ballots, has directed that such ballots be opened and counted and a revised tally of ballots issued, and no objection to such revised tally is filed by any party within 7 days after the revised tally of ballots has been made available, the regional director shall forthwith issue to the parties certification of the results of the election, including certifications of representative where appropriate, with the same force and effect as if issued by the Board. The proceeding shall thereupon be closed.

(g) *Format of filings with regional director.* All documents filed with the regional director under the provisions of this section shall be filed double spaced, on 8½ by 11-inch paper, and shall be printed or otherwise legibly duplicated. Briefs in support of exceptions or answering briefs shall not exceed 50 pages in length, exclusive of subject index and table of cases and other authorities cited, unless permission to exceed that limit is obtained from the regional director by motion, setting forth the reasons therefor, filed not less than 5 days, including Saturdays, Sundays, and holidays, prior to the date the brief is due. Where any brief filed pursuant to this section exceeds 20 pages, it shall contain a subject index with page references and an alphabetical table of cases and other authorities cited.

(h) *Extensions of time.* Requests for extensions of time to file exceptions, requests for review, supporting briefs, or answering briefs, as permitted by this section, shall be filed with the Board or the regional director, as the case may be. The party filing the request for an extension of time shall serve a copy thereof on the other parties and, if filed with the Board, on the regional director. A statement of such service shall be filed with the document.

16. Revise § 102.71(c) to read as follows:

§ 102.71 Dismissal of petition; refusal to proceed with petition; requests for review by the Board of action of the regional director.

* * * * *

(c) A request for review must be filed with the Board in Washington, DC, and a copy filed with the regional director and copies served on all the other parties within 14 days of service of the notice of dismissal or notification that the petition is to be held in abeyance. The request shall be submitted in eight copies and shall contain a complete statement setting forth facts and reasons upon which the request is based. Such request shall be printed or otherwise legibly duplicated. Requests for an extension of time within which to file the request for review shall be filed with the Board in Washington, DC, and a statement of service shall accompany such request.

Subpart D—Procedure for Unfair Labor Practice and Representation Cases Under Sections 8(b)(7) and 9(c) of the Act

17. Revise § 102.76 to read as follows:

§ 102.76 Petition; who may file; where to file; contents.

When picketing of an employer has been conducted for an object proscribed by Section 8(b)(7) of the Act, a petition for the determination of a question concerning representation of the employees of such employer may be filed in accordance with the provisions of §§ 102.60 and 102.61, insofar as applicable: *Provided, however,* That if a charge under § 102.73 has been filed against the labor organization on whose behalf picketing has been conducted, the petition shall not be required to contain a statement that the employer declines to recognize the petitioner as the representative within the meaning of Section 9(a) of the Act; or that the union represents a substantial number of employees; or that the labor organization is currently recognized but desires certification under the act; or that the individuals or labor organizations who have been certified or are currently recognized by the employer are no longer the representative; or, if the petitioner is an employer, that one or more individuals or labor organizations have presented to the petitioner a claim to be recognized as the exclusive representative of the employees in the unit claimed to be appropriate.

18. Revise § 102.77(b) to read as follows:

§ 102.77 Investigation of petition by regional director; directed election.

* * * * *

(b) If after the investigation of such petition or any petition filed under subpart C of this part, and after the investigation of the charge filed pursuant to § 102.73, it appears to the regional director that an expedited election under section 8(b)(7)(C) of the Act is warranted, and that the policies of the Act would be effectuated thereby, he shall forthwith proceed to conduct an election by secret ballot of the employees in an appropriate unit, or make other disposition of the matter: *Provided, however,* That in any case in which it appears to the regional director that the proceeding raises questions which cannot be decided without a hearing, he may issue and cause to be served on the parties, individuals, and labor organizations involved a notice of hearing before a hearing officer at a time and place fixed therein. In this event, the method of conducting the hearing and the procedure following, shall be governed insofar as applicable by §§ 102.63 to 102.69 inclusive. *Provided further, however,* That if a petition has been filed which does not meet the requirements for processing under the expedited procedures, the regional director may process it under the procedures set forth in subpart C of this part.

Subpart E—Procedure for Referendum Under Section 9(e) of the Act

19. Revise § 102.83 to read as follows:

§ 102.83 Petition for referendum under section 9(e)(1) of the Act; who may file; where to file; withdrawal.

A petition to rescind the authority of a labor organization to make an agreement requiring as a condition of employment membership in such labor organization may be filed by an employee or group of employees on behalf of 30 percent or more of the employees in a bargaining unit covered by such an agreement. The petition shall be in writing and signed, and either shall be sworn to before a notary public, Board agent, or other person duly authorized by law to administer oaths and take acknowledgments or shall contain a declaration by the person signing it, under the penalties of the Criminal Code, that its contents are true and correct to the best of his knowledge and belief. One original of the petition shall be filed with the regional director wherein the bargaining unit exists or, if the unit exists in two or more Regions, with the regional director for any of such Regions. A person filing a petition by facsimile or electronically pursuant to § 102.114(f) or (i) shall also file an original for the Agency's records, but failure to do so shall not affect the validity of the filing by facsimile, if otherwise proper. The petition may be withdrawn only with the approval of the regional director with whom such petition was filed. Upon approval of the withdrawal of any petition the case shall be closed.

20. Amend § 102.84 by revising paragraph (i), redesignating paragraph (j) as paragraph (k), and adding new paragraphs (j), (l) and (m) to read as follows:

§ 102.84 Contents of petition to rescind authority.

* * * * *

(i) The name and address of the petitioner, and the name, title, address, telephone number, fax number, and e-mail address of the individual who will serve as the representative of the petitioner and accept service of all papers for purposes of the proceeding.

(j) A statement that 30 percent or more of the bargaining unit employees covered by an agreement between their employer and a labor organization made pursuant to section 8(a)(3) of the Act, desire that the authority to make such an agreement be rescinded.

* * * * *

(l) Evidence supporting the statement that 30 percent or more of the bargaining unit employees desire to rescind the authority of their employer and labor organization to enter into an agreement made pursuant to section 8(a)(3) of the Act. Such evidence shall be filed together with the petition, but shall not be served on any other party.

(m) Evidence filed pursuant to paragraph (l) of this section together with a petition that is filed by facsimile or electronically, which includes original signatures that cannot be transmitted in their original form by the method of filing of the petition, may be filed by facsimile or in electronic form provided that the original documents are received by the regional director no later than two days after the facsimile or electronic filing.

21. Revise § 102.85 to read as follows:

§ 102.85 Investigation of petition by regional director; consent referendum; directed referendum.

Where a petition has been filed pursuant to § 102.83 and it appears to the regional director that the petitioner has made an appropriate showing, in such form as the regional director may determine, that 30 percent or more of the employees within a unit covered by an agreement between their employer and a labor organization requiring membership in such labor organization desire to rescind the authority of such labor organization to make such an agreement, he shall proceed to conduct a secret ballot of the employees involved on the question whether they desire to rescind the authority of the labor organization to make such an agreement with their employer: *Provided, however,* That in any case in which it appears to the regional director that the proceeding raises questions which cannot be decided without a hearing, he may issue and cause to be served on the parties a notice of hearing before a hearing officer at a time and place fixed therein. The regional director shall fix the time and place of the election, eligibility requirements for voting, and other arrangements of the balloting, but the parties may enter into an agreement, subject to the approval of the regional director, fixing such arrangements. In any such consent agreements, provision may be made for final determination of all questions arising with respect to the balloting by the regional director or, upon grant of a request for review, by the Board.

22. Revise § 102.86 to read as follows:

§ 102.86 Hearing; posthearing procedure.

The method of conducting the hearing and the procedure following the hearing shall be governed, insofar as applicable, by §§ 102.63 to 102.69 inclusive.

Subpart I—Service and Filing of Papers

23. Revise § 102.112 to read as follows:

§ 102.112 Date of service; date of filing.

The date of service shall be the day when the matter served is deposited in the United States mail, or is deposited with a private delivery service that will provide a record showing the date the document was tendered to the delivery service, or is delivered in person, as the case may be. Where service is made by electronic mail, the date of service shall be the date on which the message is sent. Where service is made by facsimile transmission, the date of service shall be the date on which transmission is received. The date of filing shall be the day when the matter is required to be received by the Board as provided by § 102.111.

24. Revise § 102.113(d) to read as follows:

§ 102.113 Methods of service of process and papers by the Agency; proof of service.

* * * * *

(d) *Service of other documents.* Other documents may be served by the Agency by any of the foregoing methods as well as regular mail, electronic mail or private delivery service. Such other documents may be served by facsimile transmission with the permission of the person receiving the document.

* * * * *

25. Revise § 102.114(a), (d), and (g) to read as follows:

§ 102.114 Filing and service of papers by parties; form of papers; manner and proof of filing or service; electronic filings.

(a) Service of documents by a party on other parties may be made personally, or by registered mail, certified mail, regular mail, electronic mail (if the document was filed electronically or if specifically provided for in these rules), or private delivery service. Service of documents by a party on other parties by any other means, including facsimile transmission, is permitted only with the consent of the party being served. Unless otherwise specified elsewhere in these rules, service on all parties shall be made in the same manner as that utilized in filing the document with the Board, or in a more expeditious manner; however, when filing with the Board is done by hand, the other parties shall be promptly notified of such action by telephone, followed by service of a copy in a manner designed to insure receipt by them by the close of the next business day. The provisions of this section apply to the General Counsel after a complaint has issued, just as they do to any other party, except to the extent that the provisions of § 102.113(a) or (c) provide otherwise.

* * * * *

(d) Papers filed with the Board, General Counsel, Regional Director, Administrative Law Judge, or Hearing Officer shall be typewritten or otherwise legibly duplicated on 8½ by 11-inch plain white paper, shall have margins no less than one inch on each side, shall be in a typeface no smaller than 12 characters-per-inch (elite or the equivalent), and shall be double spaced (except that quotations and footnotes may be single spaced). Nonconforming papers may, at the Agency's discretion, be rejected.

* * * * *

(g) Facsimile transmissions of the following documents will not be accepted for filing: Answers to Complaints; Exceptions or Cross-Exceptions; Briefs; Requests for Review of Regional Director Decisions; Administrative Appeals from Dismissal of Petitions or Unfair Labor Practice Charges; Objections to Settlements; EAJA Applications; Motions for Default Judgment; Motions for Summary Judgment; Motions to Dismiss; Motions for Reconsideration; Motions to Clarify; Motions to Reopen the Record; Motions to Intervene; Motions to Transfer, Consolidate or Sever; or Petitions for Advisory Opinions. Facsimile transmissions in contravention of this rule will not be filed.

* * * * *

PART 103—OTHER RULES

26. The authority citation for part 103 continues to read as follows:

Authority: 29 U.S.C. 156, in accordance with the procedure set forth in 5 U.S.C. 553.

Subpart B—[Removed and Reserved]

27. Remove and reserve subpart B, consisting of § 103.20.

Signed in Washington, DC, on June 15, 2011.

Wilma B. Liebman,

Chairman.

[FR Doc. 2011–15307 Filed 6–21–11; 8:45 am]

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FEDERAL REGISTER

Vol. 76 Wednesday,

No. 120 June 22, 2011

Part V

Department of Housing and Urban Development

24 CFR Part 30

Adjustment of Civil Money Penalty Amount for Inflation; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 30

[Docket No. FR–5490–F–01]

RIN 2501–AD52

Adjustment of Civil Money Penalty Amount for Inflation

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule.

SUMMARY: HUD is issuing this final rule to adjust for inflation the civil money penalty for failure to disclose lead-based paint hazards. This adjustment for inflation is required by the Debt Collection Improvement Act of 1996.

DATES: *Effective Date:* July 22, 2011.

FOR FURTHER INFORMATION CONTACT: Robert F. Weisberg, Acting Director, Lead Programs Enforcement Division, Office of Healthy Homes and Lead Hazard Control, Department of Housing and Urban Development, 451 7th Street, SW., Room 8236, Washington, DC 20410–3000, telephone number 202–402–7687 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to section 4 of the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note) (FCPIAA), as amended by the Debt Collection Improvement Act of 1996 (31 U.S.C. 3701 note) (DCIA), each federal agency is required to adjust, by regulation, each civil money penalty provided by law within the jurisdiction of that agency. Each such regulation must be published in the **Federal Register**.

Section 1018 of Title X of the Housing and Community Development Act of 1992 (42 U.S.C. 4852d) (Title X) and its implementing regulations at 24 CFR part 35, subpart A, requires disclosure of lead-based paint in certain sale and leasing transactions of pre-1978 housing (''Lead Disclosure Rule''). Section 1018(b)(1) of Title X (42 U.S.C. 4852d(b)(1)), referencing Section 102 of the Department of Housing and Urban Development Reform Act of 1989 (42 U.S.C. 3545), provides a monetary penalty for violations of the Lead Disclosure Rule. HUD's regulations at 24 CFR 30.65(b) currently set the maximum penalty for such violations at $11,000.

The formula for determining the specific adjustment of civil money penalties for inflation is nondiscretionary and is determined by section 5 of the FCPIAA. The adjustment is based on the change in the cost-of-living increase, which is defined in the statute as based on the percentage change, if any, in the Consumer Price Index from June of the calendar year in which the civil money penalty was last set to June of the calendar year preceding the adjustment. The statute also states specific rules for rounding, and provides that adjusted civil money penalties can only be applied prospectively; that is, only to violations that occur after the date the increase takes effect.

II. This Final Rule

This final rule applies the statutory formula to the current $11,000 maximum penalty to arrive at the updated maximum penalty. Applying the statutory formula to determine the amount of the adjustment is a four-step process. The first step entails determining the inflation adjustment factor. This is done by calculating the percentage increase by which the Consumer Price Index for all urban consumers (CPI–U) for the month of June of the calendar year preceding the adjustment (*i.e.,* June 2010) exceeds the CPI–U for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted (*i.e.,* June 1996) (the civil monetary penalty for the Lead Disclosure Rule was last set on September 24, 1996, at 61 FR 50207). CPI–U values are available at a Department of Labor, Bureau of Labor Statistics file transfer protocol site, *ftp://ftp.bls.gov/pub/special.requests/cpi/cpiai.txt.* For June 2010 and June 1996, the CPI–U values are 217.965 and 156.7, respectively. Applying these values, the inflation factor is $(217.965/156.7) - 1 = 0.39097$ or 39.097 percent.

Once the inflation adjustment factor is determined, the second step is to multiply the inflation adjustment factor by the current civil penalty amount to calculate the inflation increase. The inflation increase is $4,301 (*i.e.*, 0.39097 × $11,000). The third step is to round the inflation increase according to Section 5(a) of the FCPIAA as amended by the DCIA. Under Section 5(a), for penalties greater than $10,000 but less than or equal to $100,000, the increase must be rounded to the nearest multiple of $5,000. As such, the inflation increase here of $4,301 must be rounded to $5,000.

Once the inflation increase has been rounded, the last step is to add the rounded inflation increase to the current civil penalty amount to obtain the new, inflation-adjusted civil penalty amount. In this case, that new amount is $16,000 (*i.e.*, the current $11,000, plus $5,000 to account for inflation).

Accordingly, this rule amends 24 CFR 30.65(b) to raise the maximum penalty that HUD may impose upon those individuals or entities who violate the Lead Disclosure Rule, from $11,000 to $16,000.

Section 1018(b)(5) of Title X also authorizes the Environmental Protection Agency (EPA) to enforce Section 1018 (42 U.S.C. 4852d) requirements pursuant to Section 409 of the Toxic Substance and Control Act (TSCA) (15 U.S.C. 2689). This final rule sets the HUD penalty at the level already established by EPA (see 40 CFR 19.4).

III. Findings and Certifications

Justification for Final Rulemaking

In general, HUD publishes a rule for public comment before issuing a rule for effect, in accordance with HUD's regulations on rulemaking at 24 CFR part 10. Part 10, however, provides in § 10.1 for exceptions from that general rule where HUD finds good cause to omit advance notice and public participation. The good cause requirement is satisfied when the prior public procedure is ''impracticable, unnecessary, or contrary to the public interest.''

HUD finds that good cause exists to publish this rule for effect without soliciting public comment, on the basis that prior public procedure is unnecessary. This final rule merely follows the statutory directive in the FCPIAA to make periodic increases in HUD's civil money penalties by applying the adjustment formula established in the statute. Accordingly, because calculation of the increases is mandated by statute, HUD exercises no discretion or any policy judgment in updating the regulations to reflect the maximum allowable penalties derived from application of the statutory instructions. HUD emphasizes that this rule addresses only the matter of the calculation of the maximum civil money penalty for the violations described in the regulations. This rule does not address the issue of the Secretary's discretion to impose or not to impose a penalty, nor the procedures that HUD must follow in initiating a civil money penalty action.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements. Since this rule is published under an exception to notice

and comment rulemaking requirements, the Regulatory Flexibility Act does not apply.

Environmental Impact

This final rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Furthermore, this rule is a statutorily required establishment of a rate and cost determination and related external administrative requirements or procedures that do not constitute a development decision that affects the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(1) and (c)(6), this rule is categorically excluded from the requirements of the National Environmental Policy Act (42 U.S.C. 4332 *et seq.*).

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on state and local governments and is not required by statute, or the rule preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This final rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments and does not preempt state law within the meaning of the Executive Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This final rule does not impose any Federal mandates on any State, local, or tribal governments or the private sector within the meaning of UMRA.

List of Subjects in 24 CFR Part 30

Administrative practice and procedure, Grant programs-housing and community development, Loan programs-housing and community development, Mortgages, Penalties.

Accordingly, for the reasons stated in the preamble, HUD amends 24 CFR part 30 as follows:

PART 30—CIVIL MONEY PENALTIES: CERTAIN PROHIBITED CONDUCT

■ 1. The authority citation for 24 CFR part 30 continues to read as follows:

Authority: 12 U.S.C. 1701q–1, 1703, 1723i, 1735f–14, and 1735f–15; 15 U.S.C. 1717a; 28 U.S.C. 2461 note; 42 U.S.C. 1437z–1 and 3535(d).

■ 2. Revise § 30.65(b) to read as follows:

§ 30.65 Failure to disclose lead-based paint hazards.

* * * * *

(b) *Amount of penalty.* The maximum penalty is $16,000 for each violation.

Dated: June 11, 2011.

Shaun Donovan,

Secretary.

[FR Doc. 2011–15509 Filed 6–21–11; 8:45 am]

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FEDERAL REGISTER

Vol. 76 Wednesday,
No. 120 June 22, 2011

Part VI

The President

Proclamation 8690—Father's Day, 2011

Federal Register
Vol. 76, No. 120
Wednesday, June 22, 2011

Presidential Documents

Title 3—

The President

Proclamation 8690 of June 17, 2011

Father's Day, 2011

By the President of the United States of America

A Proclamation

Parenthood is the ultimate gift and an incredible responsibility. Every day, fathers across our country give everything they have to build a better future for their family, asking nothing in return but their children's love and success. On Father's Day, we honor the men in our lives who have helped shape us for the good, and we recommit to supporting fatherhood in our families, in our communities, and across our Nation.

Fathers, along with our mothers, are our first teachers, coaches, and advisors. They help us grow into adults, consoling us in times of need and celebrating with us in times of triumph. Strong male role models come in all forms, but they have one thing in common: they show up and give it their best. A father figure may be a biological father, or he may be a surrogate father who raises, mentors, or cares for another's child. Every family is different, but what matters is the unconditional support, guidance, and love fathers and mentors give us throughout life.

Today, too many children in our country grow up without such support and guidance. A father's absence is felt by children, families, and communities in countless ways, leaving a hole that can have lasting effects. Their absence is also felt by mothers, who work overtime and double shifts, put food on the table, and care for children alone while trying to make ends meet. And it is felt in our communities, when boys grow up without male leaders to inspire them.

My Administration has made supporting fathers and their communities a priority. Last year on Father's Day, I announced the President's Fatherhood and Mentoring Initiative, a nationwide effort to support organizations that foster responsible fatherhood and help re-engage fathers in the lives of their children. We have bolstered community and faith-based programs that provide valuable support networks for fathers. We are also promoting work-life balances that benefit families, and partnering with businesses across America to create opportunities for fathers and their children to spend time together. And military leaders are joining in our efforts to help families keep in touch when a dad is deployed overseas, so the fathers who serve to protect all our children can stay connected to their own.

On Father's Day, we celebrate the men who make a difference in the life of a child, and we pay tribute to all the fathers who have been our guiding lights. In the days ahead, we recommit ourselves to making fatherhood, and the support men need to be fathers, a priority in our Nation.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, in accordance with a joint resolution of the Congress approved April 24, 1972, as amended (36 U.S.C. 109), do hereby proclaim June 19, 2011, as Father's Day. I direct the appropriate officials of the Government to display the flag of the United States on all Government buildings on this day, and I call upon all citizens to observe this day with appropriate programs, ceremonies, and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this seventeenth day of June, in the year of our Lord two thousand eleven, and of the Independence of the United States of America the two hundred and thirty-fifth.

[FR Doc. 2011–15780
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Billing code 3195–W1–P

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Federal Register

Vol. 76, No. 120

Wednesday, June 22, 2011

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Public Laws Update Service (numbers, dates, etc.)	**741–6043**
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FEDERAL REGISTER PAGES AND DATE, JUNE

31451–31784 1
31785–32064 2
32065–32312 3
32313–32850 6
32851–33120 7
33121–33612 8
33613–33966 9
33967–34142 10
34143–34572 13
34573–34844 14
34845–35094 15
35095–35300 16
35301–35712 17
35713–35956 20
35957–36280 21
36281–36856 22

CFR PARTS AFFECTED DURING JUNE

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

2 CFR

780 34143
782 34573

Proposed Rules:

Ch. XI 32330
Ch. XVIII 31884
Ch. XXIV 31884
Ch. XXVII 34003

3 CFR

Proclamations:

8683 32065
8684 32851
8685 32853
8686 32855
8687 32857
8688 33119
8689 35089
8690 36855

Executive Orders:

13575 34841
13576 35297
13577 35715

Administrative Orders:

Memorandums:
Memorandum of May 31, 2011 33117
Memorandum of June 6, 2011 33613
Notice of June 14, 2011 35093
Notice of June 17, 2011 35955
Presidential Determinations:
No. 2011-10 of June 3, 2011 35713
No. 2011-11 of June 8, 2011 35719

5 CFR

531 32859
532 31785
Ch. LXX 35957

Proposed Rules:

Ch. I 31886
532 31885
Ch. VII 32088
Ch. XXVI 32330
Ch. XXVIII 34003
Ch. XXXV 31886
Ch. XLII 34177
Ch. XLV 32330
Ch. LIX 31884
Ch. LXV 31884

6 CFR

Proposed Rules:

Ch. I 32331
5 ..... 34177, 34616

7 CFR

51 31787
201 31790
210 ..... 34542, 35301
215 34542
220 34542
225 34542
226 34542
246 35095
457 32067
932 35957
953 33967
985 33969
1206 36281
3430 ..... 35318, 35319

Proposed Rules:

36 31887
205 ..... 31495, 34180
271 35787
273 35787
281 35787
916 31888
917 31888
958 35997
983 34181
987 34618
1170 34004
1205 32088
3434 34187

8 CFR

214 33970

Proposed Rules:

Ch. I 32331
Ch. V 34003

9 CFR

307 33974
381 33974
590 33974

Proposed Rules:

92 31499
93 31499
94 31499
96 31499
98 31499

10 CFR

20 35512
30 35512
40 35512
50 ..... 35512, 36232
70 35512
72 ..... 33121, 35512
170 36780
171 36780
217 33615
430 31750
431 ..... 31795, 33631

Proposed Rules:

30 36386
35 33173

40 31507
50 ....32878, 34007
72 35137
73 35137
150 31507
430 34914
431 34192

11 CFR

Proposed Rules:
109 36000
114 36001

12 CFR

202 31451
213 35721
225 35959
226 ....35722, 35723
309 35963
310 35963
651 35966
652 35966
914 33121
1229 35724
1235 33121
1237 35724
1732 33121
Proposed Rules:
4 32332
5 32332
7 32332
8 32332
28 32332
34 32332
43 34010
225 35351
244 34010
373 34010
652 35138
Ch. XVII 31884
1234 34010
1236 35791

13 CFR

124 33980

14 CFR

1 34576
23 33129
25 ....31451, 31453, 31454, 31456, 33129, 35324, 35736
27 33129
29 33129
33 33981
39 ....31457, 31459, 31462, 31465, 31796, 31798, 31800, 31803, 33982, 33984, 33986, 33988, 33991, 35327, 35330, 35334, 35336, 35340, 35342, 35344 35346, 36283
71 ....31821, 31822, 34576, 35097, 35966, 35967, 36285, 36286
91 31823
93 34576
95 33136
97 ....35098, 35101
121 35103
135 35103
417 33139
Proposed Rules:
21 36001
36 36001
39 ....31508, 32103, 33173, 33176, 33658, 33660, 34011, 34014, 34625, 34918, 36011, 36387, 36390, 36392, 36395, 36398
71 ....31510, 32879, 34196, 34627, 35362, 35363, 35369, 35370, 35371, 35799, 36014, 36017
139 32105
217 31511
241 31511
298 31511
382 32107
Ch. V 31884

15 CFR

732 35276
738 35276
740 ....34577, 35276
743 ....34577, 35276
774 ....34577, 35276

16 CFR

259 31467
Proposed Rules:
309 31513
1460 33179

17 CFR

200 35348
240 ....34300, 34579, 36287
249 34300
Proposed Rules:
1 ....32880, 33066, 35372
5 33066
7 33066
8 33066
15 33066
18 33066
21 33066
22 ....31518, 33818, 35141
36 33066
41 33066
140 33066
145 33066
155 33066
166 33066
190 ....31518, 33818, 35141
230 ....31518, 34920
232 33420
239 31518
240 ....32880, 33420, 34920
246 34010
249 33420
249b 33420
260 34920

18 CFR

Proposed Rules:
Ch. I 36400

19 CFR

122 31823
Proposed Rules:
Ch. I 32331

20 CFR

Proposed Rules:
Ch. III 31892
Ch. IV 34177
Ch. V 34177
Ch. VI 34177
Ch. VII 34177
Ch. IX 34177

21 CFR

5 31468
10 31468
14 31468
19 31468
20 31468
21 31468
201 ....35620, 35665
310 ....35620, 35665
312 32863
314 31468
320 32863
333 36307
350 31468
516 31468
814 31468
874 34845
1141 36628
1310 31824
Proposed Rules:
Ch. I 32330
Ch. II 34003
201 ....35672, 35678
310 35678
352 35669
573 32332
600 36019
610 36019
680 36019

22 CFR

62 33993
208 34143
210 34573

23 CFR

Proposed Rules:
627 36410

24 CFR

30 36850
Proposed Rules:
Ch. I 31884
Ch. II 31884
267 34010
Ch. III 31884
Ch. IV 31884
Ch. V 31884
Ch. VI 31884
Ch. VIII 31884
Ch. IX 31884
Ch. X 31884
Ch. XII 31884

25 CFR

Proposed Rules:
Ch. I 33180
Ch. III 33181
Ch. V 32330

26 CFR

1 ....33994, 33997
31 32864
Proposed Rules:
1 ....31543, 32880, 32882, 34017, 34019
31 32885
301 31543
405 36178
406 36178

27 CFR

Proposed Rules:
Ch. II 34003

28 CFR

Proposed Rules:
Ch. I 34003
104 36027
III 34003
V 34003
VI 34003

29 CFR

1910 33590
1915 33590
1917 33590
1918 33590
1919 33590
1926 33590
1928 33590
4001 34590
4022 ....34590, 34847
4044 ....34590, 34847
Proposed Rules:
Ch. II 34177
Ch. IV 34177
Ch. V 34177
Ch. VII 34177
101 36812
102 36812
103 36812
1602 31892
1904 36414
Ch. XXV 34177
2550 31544

30 CFR

75 35968
950 34816
Proposed Rules:
Ch. I 34177
75 35801
104 35801
906 36039
950 36040

31 CFR

10 32286
500 35739
505 35739
510 35740
545 31470
Proposed Rules:
Ch. IX 34003

32 CFR

706 32865
Proposed Rules:
Ch. I 32330
Ch. V 32330
Ch. VI 32330
Ch. VII 32330
Ch. XII 32330

33 CFR

1 31831
27 31831
96 31831
100 ....32313, 34606, 36308, 36311
101 31831
107 31831
110 35742
115 31831
117 ....31831, 31838, 34848, 35349, 35978
135 31831
140 31831
148 31831
150 31831
151 31831
160 31831

161 31831
162 31831
164 31831
165 ....31839, 31843, 31846, 31848, 31851, 31853, 32069, 32071, 32313, 33151, 33154, 33155, 33157, 33639, 33641, 33643, 33646, 34145, 34852, 34854, 34855, 34859, 34862, 34867, 34869, 35104, 35106, 35742, 36314, 36316, 36318
166 31831
167 31831
169 31831
175 33160
183 33160
Proposed Rules:
Ch. I 32331
100 ....35802, 36438
110 34197
165 ....31895, 36438, 36447
167 35805
175 35378
183 35378
Ch. II 32330
334 35379

34 CFR

Ch. II 32073
222 31855
668 34386

36 CFR

Proposed Rules:
Ch. III 32330

37 CFR

201 32316

38 CFR

18 33999
21 33999
Proposed Rules:
17 35162

39 CFR

111 34871
952 36320

40 CFR

52 ....31856, 31858, 32321, 33647, 33650, 33651, 34000, 34608, 34872, 36326, 36329
63 35744
98 36339
180 ....31471, 31479, 31485, 34877, 34883, 36342, 36349, 36356
262 36363
268 34147
271 34147
300 32081
Proposed Rules:
Ch. I 35383
51 36450
52 ....31898, 31900, 32110, 32113, 32333, 33181, 33662, 34020, 34021, 34630, 34935, 35167, 35380, 36468, 36471
63 35806
81 36042
86 32886
98 36472
174 ....33183, 36479
180 ....33184, 34937, 36479
262 36480
268 34200
271 34200
300 32115
Ch. IV 34003
Ch. VII 32330

41 CFR

302-16 35110
Proposed Rules:
Ch. 50 34177
Ch. 60 34177
Ch. 61 34177
Ch. 101 32088
Ch. 102 32088
102-34 31545
Ch. 105 32088
Ch. 128 34003
60-250 36482
60-300 36482
301-11 32340
302-2 32340
302-3 32340
302-17 32340

42 CFR

100 36367
412 32085
434 32816
438 32816
447 32816
Proposed Rules:
Ch. I 32330
5 31546
84 33188
401 33566
412 34633
413 34633
414 ....31547, 32410
476 34633
485 35684
Ch. V 32330

44 CFR

64 ....34611, 36369
65 35753
67 ....35111, 35119, 36373
Proposed Rules:
Ch. I 32331
67 ....32896, 36044, 36482

45 CFR

Proposed Rules:
Ch. II 32330
Ch. III 32330
Ch. IV 32330
Ch. V 34003
Ch. VIII 31886
Ch. X 32330
Ch. XIII 32330

46 CFR

45 32323
Proposed Rules:
Ch. I 32331
Ch. III 32331
10 35169
12 35173
515 34945

47 CFR

1 32866
2 33653
73 ....33656, 36384
80 33653
90 33653
Proposed Rules:
4 33686
11 35810
15 35176
27 32901
73 ....32116, 35831
74 35181
76 32116
78 35181
101 35181

48 CFR

203 32840
211 33166
212 33170
225 ....32841, 32843
246 33166
252 ....32840, 32841, 33166
539 34886
552 34886
Proposed Rules:
Ch. 1 ....32133, 32330
2 32330
8 34634
9 34634
17 31886
21 31886
52 ....32330, 34634
54 32330
203 32846
204 32846
252 ....32845, 32846
Ch. 5 32088
Ch. 16 31886
Ch. 18 31884
Ch. 24 31884
Ch. 28 34003
Ch. 29 34177
Ch. 61 32088

49 CFR

171 32867
177 32867
192 35130
195 35130
213 34890
383 32327
390 32327
572 31860
Proposed Rules:
390 32906
391 34635
396 32906
541 36486
Ch. XII 32331

50 CFR

17 ....31866, 33036, 35349, 35979
217 ....34157, 35995
223 35755
300 34890
600 34892
622 ....31874, 34892
635 32086
648 ....31491, 32873, 34903
660 ....32876, 34910
679 ....31881, 33171
680 ....35772, 35781
Proposed Rules:
17 ....31686, 31903, 31906, 31920, 32911, 33880, 33924, 36049, 36053, 36068, 36491, 36493
20 36508
223 ....31556, 34023
224 31556
226 32026
635 36071
648 ....34947, 35578, 36511
660 33189
665 32929

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws*.

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H.R. 754/P.L. 112–18

Intelligence Authorization Act for Fiscal Year 2011 (June 8, 2011; 125 Stat. 223)

Last List June 6, 2011

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